AMPAİİİ 受理号: JQZ2100549

医疗器械产品注册技术审评报告 产品中文名称: 一次性使用前列腺热蒸汽治疗器械

HUKK

,由于文句小:一次性使用前列腺热蒸汽治疗器械产品英文(原文)名称: Rezum Delivery Device产品管理类别:第三类申请人名称: Boston Scientific Corporation

cmde.org.cn

A TOP OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE P

All Innin Chile or of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile

10°C

W. Chole oto.

国家药品监督管理局医疗器械技术审评中心

目 录

AMP ARTHUR IN THE REAL PROPERTY OF THE PARTY
AND ATHER PROPERTY.

の大学後

). Williams		FINE	W. C.	O S	XXXXXX
W. CL	*		A THE WAY OR	X IJ CHO	3.0
cmde.ord.	本信 申 申 生 评 临 临 临 序 化 上 平 概述 照 概述 照 概述 照 概述 照 概述 照 概述 照 概述 照 概述	目录	AMP ATTE	3 	× 300
X	1-11-0		Hull	3	And Ch.
WIN CO.	申请人名称			~ V · · · ·	
	申请人住所			3	
一、 技 <i>/</i>	术审评概述		X	4	AR ARRIVERS
RATE,	申请人名称	20.	-C	4	
	临床前研究概述	·	(O) (X)	5	4
四、	临床评价概述 产品受益风险判定.	W. J. Cillian		9	<u> </u>
沙工	分评价意见	Winn.	X 16.		7
A CO	FINE		SVIII WANG	We old in the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the contraction of the	. 117
O.	<u> </u>	A PART IN		inde.	A A A A A A A A A A A A A A A A A A A
O.		The state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the s	THE THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF T		(A)
O.C. O.C. O.C. O.C. O.C. O.C. O.C. O.C.			3/2	Hilliam)
XX de.				NA THE	XXX

No of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of the last of

M.c.mde.ord.c.n

基本信息

AMP WHITE IN THE PROPERTY OF THE PARTY OF TH

wind chide order

AMPA

HUKK

A STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STA

A TOP OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE P

10°C

W. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clude or o. clu

AND THE REAL PROPERTY OF THE PARTY OF THE PA

Boston Scientific Corporation

申请人名称 Boston Scient AMP ATATION OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE 生产地址
4100 Hamline Ave N Saint Paul, MN USA 55112 三、生产地址
4100 Har 300 Boston Scientific Way, Marlborough, MA 01752, USA

, MN ÜS WIND WAR CHARLES TO SEE THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE

る人様後

WIND WHITE IN THE REAL PROPERTY OF THE PARTY
技术审评概述

AND WHITE HAR IN THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE SERVICE OF THE

whith chide order

wind child

cmde order

(一)产品结构及组成

产品概述 产品由热蒸汽治疗器械,输水装置和插针接头组成。其中 治疗器械由手柄(含蒸汽产生装置)、鞘管(含蒸汽传输导管)、 无菌水管、冲洗管、排水管组成。产品均为环氧乙烷灭菌, 次性使用,有效期2年。

(二)产品适用范围

该产品在医疗机构使用,与本公司生产的 Rezum 热蒸汽治 疗设备配合使用,用于缓解与良性前列腺增生(BPH)相关的 症状和梗阻,适用于50岁(含)以上男性前列腺体积(伴或不 伴前列腺中央区和/或中叶增生)为30-80cm3的良性前列腺增生 www.chde.org 患者。需配合 4mm/30°/30cm 的膀胱内窥镜使用。

(三)型号/规格

一IF/// 一 本产品为前列腺热蒸汽治疗器械,与本公司生产的热蒸汽设备配合使用,利用主机提供的电能将开带工,通过前端的可伸缩和 治疗设备配合使用,利用主机提供的电能将无菌水加热成为热 蒸汽,通过前端的可伸缩针头穿刺深入到前列腺组织中,利用

蒸汽热量对前列腺组织进行加热以减少前列腺体积, 前列腺增生的相关症状和梗阻。治疗器械前端鞘管内含内窥镜 通道,可置入 4mm 直径的膀胱内窥镜用于观察治疗部位,还可 输出生理盐水用于冲洗和清理视野。治疗器械手柄内含加热线 圈作为蒸汽产生装置,并在线圈和蒸汽输出口设有温度传感器, 可监测相应部位的温度参数并传输给主机,以监测产品的工作

MAN CHILL

临床前研究概述

(一)产品性能研究

申请人提供了产品性能研究资料以及产品技术要求的研究 和编制说明,给出了机械性能、尺寸、耐压、温度、蒸汽相关 参数、化学性能、无菌、耐腐蚀性等功能性、安全性指标以及 与质量控制相关的其他指标的确定依据。提供了产品温度传感 器的设计规范和图纸, 以及所符合的相关标准, 可支持产品所 宣称的温度测量范围及精度。

(二)生物相容性

人体部分的生物相容性进行了评价。所评价材料短时接触人体黏膜和组织,分别实施了生物学试验(细晌丰!! 致敏、急性人力 依据 GB/T 16886.1-2011 对成品中与患者直接或间接接触 报告。针对产品中与蒸汽接触部位,申请人对输出蒸汽进行了 浸提物质的化学表征分析,检测结果显示蒸汽中所含有害物质 未超出安全性限值,并提供了毒理学阈值的相关依据,可证实 高温蒸汽未对所接触材料产生额外的生物学风险。

MANCHIN

(三)灭菌

产品由生产企业进行环氧乙烷灭菌,无菌保证水平为 10⁻⁶,申请人依据 ISO 11135 标准进行灭菌确认,提交了灭菌确认报告。采用强制解析和自然解析相结合的方式去除残留,提交了EO和 ECH 的残留量测试报告。

(四)产品有效期和包装

产品为一次性使用,货架有效期 2 年,申请人通过加速老化方式进行验证,对老化后的产品进行性能和包装完整性的测试,证实产品可满足 2 年的有效期。

(五) 动物研究

申请人提供了产品在境外开展的基于犬模型的动物试验, 选择其他原理的治疗设备进行动物前列腺消融对照试验, 观察即刻和1天后的组织变化情况。结果显示二者均能实现有效的前列腺组织体积减小, 试验组与对照组相比周边组织损伤程度较小。

(六)有源设备安全性指标

NA THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF TH

产品符合医用电气相关通用安全标准(GB 9706.1-2007)和并列安全标准(YY 0505-2012)的要求,提供由医疗器械检验机构出具的符合标准要求的检验报告。

MAN CHILL

三、临床评价概述

该产品采用境外临床试验路径进行临床评价,境外临床试验采用前瞻性、多中心、单盲、随机对照、优效性临床试验设计。

临床试验在 15 家境外临床机构开展,入组受试者 197 例 (治疗组 136 例,对照组 61 例),术后 3、6、12 个月进行随访,随后每年进行随访至术后 5 年。对照组受试者在术中采用的是与试验组 Rezum 尺寸基本相同的硬性膀胱检查镜(19F-21F)模拟治疗手术进行对照治疗。术后随访 3 个月后,符合治疗组入组标准的对照组受试者采用试验器械进行交叉治疗(53 例),不进行交叉治疗的对照组受试者随访至 6 个月。主要有效性终点为治疗组与对照组在基线至术后 3 个月时国际前列腺症状评分(IPSS)评分变化评估 BPH 症状改善情况的对比。主要安全性终点为术后 3 个月时试验器械相关严重并发症的发生率,其目标值为 12%;次要有效性终点为术后 3 个月、6 个月和 12 个月时的受试者应答者(治疗后 IPSS 评分较基线改善 30%或其以上)百分比。

主要有效性终点在术后3个月时,治疗组和对照组IPSS评分较基线的变化分别为-11.2、-4.3,治疗组的改善情况平均值与对照组相比,优效性假设成立,符合预先规定的主要有效性终点。治疗组发生1例符合方案定义的器械相关严重并发症,发生率为0.7%,置信区间(CI)上限为3.4%,小于预设目标值12%(p<0.0001)。本项临床试验结果达到预先设定的主要有效性终点和主要安全性终点。

MAN CHIN

治疗组 3 个月时的应答率为 77.94%,对照组为 34.43%,治疗组的应答率高于对照组,差异有统计学意义 (p<0.0001),符合预先规定的次要疗效终点 S1。治疗组 6 个月时的应答率为 75.00%,显著高于预先规定的 40%,符合次要疗效终点 S2 (p<0.0001)。治疗组术后 12 个月时的应答率为 75.00%,显著高于预先规定的 40%,符合次要疗效终点 S3 (p<0.0001)。申请人提交的长期随访数据显示,术后 2 年、3 年、4 年和 5 年时治疗组受试者应答率分别为 74.81%(101/135)、71.11%(96/135),61.48% (83/135) 和 60.74% (82/135)。

经技术审评,申请人提供的临床评价资料符合目前的审评要求。

此外,申请人提交了申报产品在海南博鳌乐城医疗先行区开展的真实世界临床研究资料。

A THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE

M.chde.org.ch

All Innin Chile or of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile of the Chile

N. M. CO.

A HARLES

A STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STA 一、产品受益风险判定 申请人参照 YY/T 0316-2016 标准对该产品上市可能带来的 佥进行了分析、评价,采取了合理的风险控制方案,经证 「剩余风险在可接受范围内。根据申请人^坦" 合评价,在目前认知水平 ¹ 来的受益大干^四 cinde ordich 申请人参照 YY/T 0316-2016标准对该产品上市可能带来的风险进行了分析、评价,采取了合理的风险控制方案,经评估认为剩余风险在可接受范围内。根据申请人提供的申申生经综合评价,在目前认知水平" AMPAIRE AMP Addition of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract o

AMP AFFIFE MANN. CINDER OF OF STREET STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, STREET, S

るな様々

AMP ARTHUR AREA OF THE REAL PROPERTY OF THE PARTY OF THE

综合评价意见 该产品为首个申报的同品种医疗器械。依据《医疗器械监督管理条例》(国务院令第 680 号),《医疗器械注册管理办法》 (国家食品药品监督管理总局令第 4 号)等相关医疗器械注 与配套规章、经对申请人提交的注册申报资料进 报产品符合安全性、有效性的要求 cinde ordich AMIP REFERENCE OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF * MAN CHORE 2022年2月28

-月28日 ANN ANN CITATION OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE









AMP ATHE MAIN CHANGE

の大学後

A THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE

WEB TRAINING CENTER