|  |  |
| --- | --- |
|  | *{填写申请者的企业名称}*  *{填写申请者的企业地址}（参考示例：1201, Haosheng Business Center, 4096 Dongbin Road, Nanshan, Shenzhen, P.R.C）*  Tel: *{填写申请者的电话}* Fax: *{填写申请者的传真}* |
| ***{填写申请日期 }（参考示例：Arpil 22, 2021）*** |  |
| Food and Drug Administration  Center for Devices and Radiological Health  Document Control Center - WO66-G609  10903 New Hampshire Avenue  Silver Spring, Maryland 20993-0002 | Reference: 510(k) Premarket Notification: Request for FDA Review  510(k) submitter: *{填写申请者的企业名称}* |

Type of Submission: Traditional 510(k)

Trade/Device Name: ***{填写申报产品名称 }***

Common Name: ***{填写申报产品通用名称 }***

Model : ***{填写申报产品的具体型号}***

Dear Sir/Madam:

***{填写申请者的企业名称}*** is submitting one original paper copy and one electronic copy (CD copy) of the Premarket Notification for the ***{填写申报产品名称}*** to review. I certify that the electronic copy of the submission is being provided as complete and accurate copy of the original 510(k).

This submission is being made in accordance with Section 510(k) of the Food , Drug and Cosmetic Act, in conformance with 21 CFR Part 807 and the FDA Guidance “Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, September 13, 2019” as described in the actual 510(k) submission.

If there are any questions, please contact me at ***{填写FDA联系人的联系电话 }（参考示例：0086-755-86664986）.***

**eCopy Statement:**

**The eCopy is an exact duplicate of the paper copy.**

Sincerely,

***{填写申请者的企业名称}***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Company Representative for

***{填写申请者的企业名称}***

Enclosure

**510(k) Cover Letter**

***{填写申请日期 }（参考示例：Arpil 22, 2021）***

Food and Drug Administration   
Center for Devices and Radiological Health  
Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby made of the intention of ***{填写申请者的企业名称}*** to introduce into interstate commerce for commercial distribution ***{填写申报产品名称}***.

The information contained in this notification and our intent to market this device is considered confidential commercial information and we request that the FDA consider it as such (per 21 CFR 807.95). The company has taken reasonable precautions to protect this confidentiality.

The following information is being submitted for a traditional 510(k) in conformance with 21 CFR Part 807.87, and the FDA Guidance “Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, September 13, 2019” the sequence of information listed below in the 510(k) cover letter is following the guidance’s order.

1. **Basic Information**

**1.1 Administrative Information**

|  |  |
| --- | --- |
| Submission Sponsor | ***{填写申请者的企业名称}*** |
| Address | ***{填写申请者的企业地址}（参考示例：1201, Haosheng Business Center, 4096 Dongbin Road, Nanshan, Shenzhen, P.R.C）*** |
| Contact Persons: | **Primary Contact Person：**  ***{填写联系人的姓名}{填写联系人的职位}***  ***{填写联系人的企业名称 }***  ***{填写联系人的企业地址}（参考示例：1201, Haosheng Business Center, 4096 Dongbin Road, Nanshan, Shenzhen, P.R.C）***  Tel: ***{填写联系人的电话}***  Fax: ***{填写联系人的传真}***  E-mail: ***{填写联系人的邮箱}***  **Secondary Contact Person**  ***{填写联系人的姓名}{填写联系人的职位}***  ***{填写联系人的企业名称 }***  ***{填写联系人的企业地址}（参考示例：1201, Haosheng Business Center, 4096 Dongbin Road, Nanshan, Shenzhen, P.R.C）***  Tel: ***{填写联系人的电话}***  Fax: ***{填写联系人的传真}***  E-mail: ***{填写联系人的邮箱}*** |

***【联系人可以是咨询公司，建议至少第二联系人是申请人企业的有一定职位的人员】***

**1.2 Trade Name (Proprietary Name)**

***{填写申报产品名称 }***

Models: ***{填写申报产品的具体型号}***

**1.3 Common Name:**

***{填写申报产品通用名称 }***

**1.4 Regulatory Class:**

***{填写产品的法规分类}（参考示例：Class II）***

**1.5 Classification Name:**

***{填写产品的分类名称 } 【可以在FDA网站查询对应代码产品的Classification Name】***

**1.6 Regulation Number**

***{填写法规编号 } 【可以在FDA网站查询对应代码产品的Regulation Number】***

**1.7 Product Code:**

***{填写产品代码 }***

**1.8 Classification Panel:**

***{填写分类模块 } 【可以在FDA网站查询对应代码产品的Classification Panel】***

**1.9 Type of 510(k) submission**

Traditional 510(k)

**1.10 Establishment registration number**

NA***【如果企业已经有登记列名账号，可以填写具体的登记列名账号】***

**1.11 Preference for continued confidentiality**

The information contained in this notification and our intent to market this device is considered confidential commercial information and we request that the FDA consider it as such (per 21 CFR 807.95). The company has taken reasonable precautions to protect this confidentiality.

**1.12 Predicate device information**

|  |  |  |
| --- | --- | --- |
| **Manufacturer** | **Device Name** | **510(K) Number** |
| ***{填写对比产品的企业名称}*** | ***{填写对比产品的器械名称，需要与对应K summary中的名称一致 }*** | ***{填写对比产品的K Summary }*** |

**1.13 Any FDA document numbers associated with prior formal correspondence with FDA related to the device**

None. ***【如果前期与FDA已经沟通过产品的相关事宜，则需要提供与FDA沟通过程涉及的文件号】***

**1.14 Statement of no prior submission for the subject device**

There is no any FDA document numbers associated with prior formal correspondence with FDA.***【如果前期与FDA已经沟通过产品的相关事宜，则填写NA】***

**1.15 Other**

No applicable mandatory performance standards or special controls exist for this device.

**2 Basis for the Submission**

**2.1 The basis reason for the submission**

The basis and reason for the Traditional 510(k) is a new device.

**2.2 Previous Submission**

There were no prior submissions for the subject device and ***{填写器械名称}*** has not been previously submitted to the FDA for this or any other indication.

**3. Design and Use of the device**

**3.1 Intended for Use**

***{填写产品预期用途 }***

**3.2 General Device Description**

***{填写产品描述 }***

**3.3 Device characteristics**

|  |  |
| --- | --- |
| Table 1. Design and Use of the Device | |
| Question | Answer (YES/No) |
| Is the device intended for prescription use (21 CFR 801 Subpart D)? | No |
| Is the device intended for over-the counter use (21 CFR 807 Subpart C)? | Yes |
| Does the device contain components derived from a tissue or other biologic source? | No |
| Is the device provided sterile ? | No |
| Is the device intended for single use? | Yes |
| Is the device a reprocessed single use device? | No |
| Does the device contain a drug? | No |
| Does the device contain a biologic? | No |
| Does the device use software? | No |
| Does the submission include clinical information ? | No |
| Is the device implanted? | No |

1. **Product specific guidance**

None ***【如果器械涉及专门的指南，则需要记录该指南，并根据指南，罗列产品对应的信息】***

Additional Information: Quality Assurance and Manufacturing Controls:

The ***{填写器械名称}*** (models: ***{填写器械型号}***) operates in compliance with FDA's Good Manufacturing Practice Regulations for Medical Devices (21 CFR Part 820) and a formally established and controlled Quality System Program. Devices will be manufactured and assembled to established and controlled device master record requirements by formally trained and supervised personnel.

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA. Our intent to market this device is not considered public information and we have taken precautions to protect this confidentiality. We would appreciate your reviewing this information at your earliest convenience so that a prompt reply to our request for 510(k) clearance can be processed.

Sincerely,

***{填写申请企业名称}***