**Comprehensive Device Description and Principles of Operation Documentation**

**1. Device Information**

Device Name: ***{填写申报产品名称 }***

Models: ***{填写申报产品的具体型号}***

Common Name: ***{填写申报产品通用名称 }***

Regulatory Class: II

Classification Name and Product Code:

***{填写产品的分类名称 } {填写产品代码 } （21 CFR 880.2910 Clinical electronic thermometer (FLL)）***

**2. Submission Sponsor**

***{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）***

**3. Indications for Use**

***{填写产品适应症 }***

**4.General Description**

**4.1 Introduction**

***{填写器械简单的描述 }***

**4.2 Power source**

***{填写器械的功率 }***

**4.3 Composition and functions**

***{填写器械的组成和功能 }***

**4.4 Description a typical device with which the accessory or component will be used**

***{如果器械与其他组件或附件一起使用，填写器械怎么与组件或附件一起使用 }***

**5.A device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.**

The device does not have a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.

***【如果有产品专用的指南，则填写对应的指南】***

**6.Descriptive information is present and consistent within the submission**

The device description section is consistent with the device description in the labeling.

**7.The submission includes descriptive information for the device**

**7.1 A description of the principle of operation or mechanism of action for achieving the intended effect**

***{填写器械的操作原理和作用机理}***

**7.2 A description of proposed conditions of use**

***{填写预期的使用环境，以及预期的适用人群}***

**7.3 A list and description of each device for which clearance is requested**

The clearance of ***{填写器械名称，及所有型号}*** are request. The details of the description of each device can refer to Table 1. Complete Description of Device Specifications.

Table 1. Complete Description of Device Specifications

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Item**  | **Model 1** | **Model 2** | **Model 3** | **........** |
| 1 | ***{填写对应的项目}*** | ***{填写对应的内容}*** | ***{填写对应的内容}*** | ***{填写对应的内容}*** | **........** |
| 2 | ***{填写对应的项目}*** | ***{填写对应的内容}*** | ***{填写对应的内容}*** | ***{填写对应的内容}*** | **........** |
| 3 | ***{填写对应的项目}*** | ***{填写对应的内容}*** | ***{填写对应的内容}*** | ***{填写对应的内容}*** | **........** |
| 4 | **........** | **........** | **........** | **........** | **........** |

**7.4 Representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device.**

7.4.1 Structural drawings of the device

***{填写器械结构图}***

7.4.2 Pictures of the device

The picture of the ***{填写器械名称}*** is as below.

***{填写器械图片}***

**8.Device is intended to be marketed with accessories and/or as part of a system.**

The device is not intended to be marketed with accessories and/or as part of a system.

***【如果器械需要与产品附件一起使用，则需要填写产品附件信息】***

**9. Patient Contact Material**

The list of all patient contacting components as follows.

***{填写与人体直接或间接接触的材料的信息}***

*（****参考示例：***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Device Components*** | ***Contact with human body*** | ***Contact Method*** | ***Contact classification*** | ***Tissue-contacting device component*** |
| ***Category*** | ***Contact Duration*** | ***Materials*** | ***Additive*** |
| *Film* | *Oral cavity and axillary cavity* | *Direct contact*  | *Surface contacting* | *Less than 24 hour duration* | *PE(100%)* | *Do not contains additive* |

*）*

***【如果产品还有颜色添加剂，则需要明确颜色添加剂的成分，颜色添加剂需要符合CFR中颜色添加剂的相关要求】***