**510(k) Summary**

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Summary：***{填写申请日期 }（参考示例：Arpil 22, 2021）***

1. **Submitter**

***{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）***

1. **Contact Person**

**2.1 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}***

**2.2 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}***

1. **Date Prepared: *{填写申请日期 }（参考示例：Arpil 22, 2021）***
2. **Proposed Device Information**

Trade name: ***{填写申报产品名称 }***

Model: ***{填写申报产品的具体型号}***

Common name: ***{填写申报产品通用名称 }***

Classification name:***{填写产品的分类名称 }（Clinical electronic thermometer）***

Review Panel: ***{填写法规编号 }（General Hospital）***

Product Code: ***{填写产品代码 }（FLL）***

Regulation Class: II

Regulation Number:***{填写法规编号 }（*** ***21 CFR 880.2910）***

1. **Predicate Device Information**

|  |  |  |
| --- | --- | --- |
| **Manufacturer**  | **Device Name** | **510(K) Number**  |
| ***{填写对比器械制造商名称}*** | ***{填写对比器械名称 }*** | ***{填写对比器械K号 }*** |

1. **Device Description**

***{填写器械描述}***

1. **Intended use**

***{填写器械预期用途}***

1. **Comparison to Predicate Device**

The ***{填写器械名称}*** have the same intended use, similar technological characteristics as the following predicate device and are substantially equivalent with regards to safety and effectiveness.

***{填写对比器械K号}{填写对比器械名称 }***, manufactured by ***{填写对比器械制造商 }***

The following table shows similarities and differences of technological characteristics between our device and the predicate devices.

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** |  **Proposed Device** | **Predicate Devices**  | **Remark** |
| Trade Name  | ***{填写申报器械信息}*** | ***{填写对比器械信息}*** | / |
| Model  | ***{填写申报器械信息}*** | ***{填写对比器械信息}*** | / |
| 510(k) Submitter | ***{填写申报器械信息}*** | ***{填写对比器械信息}*** | / |
| 510(k) Number  | ***{填写申报器械信息}*** | ***{填写对比器械信息}*** | / |
| Classifications Name & Citations | ***{填写申报器械信息}*** | ***{填写对比器械信息}*** | Same |
| IntendedUse  | ***{填写申报器械信息}*** | ***{填写对比器械信息}*** | Same |
| ***{填写其******他对比项}******（参考示例：Use type）*** | ***{填写申报器械信息}******（参考示例：******For single use）*** | ***{填写申报器械信息}******（参考示例：******For single use）*** | Same |
| ***{填写其******他对比项}******（参考示例：Sterile*** ***Package）*** | ***{填写申报器械信息}******（参考示例：******Non-sterile package）*** | ***{填写申报器械信息}******（参考示例：******Non-sterile package）*** | Same |
| ***{填写其******他对比项}******（参考示例：Size）*** | ***{填写申报器械信息}******（参考示例：******125×30mm;*** ***150×40mm;*** ***125×40mm;*** ***150×70mm;*** ***235×50mm;*** ***235×70mm;）*** | ***{填写对比器械信息}******（参考示例：******94×26mm）*** | Different 1 |
| ***{填写其******他对比项}*** | ***{填写申报器械信息}*** | ***{填写对比器械信息}*** | Different 2 |
| ..... |  |  |  |

Our device and the predicate device differ in the following areas.

(1) Different 1: ***{填写对比项}（参考示例：Size）***

***【填写差异不影响产品安全有效的说明,对于安全有效性的解释说明，一般有以下几个方向：***

***产品设计方面；***

***产品临床使用方面；***

***产品符合标准方面；***

***.......***

***】***

***（参考示例1：The size of single piece of proposed device is varied size. While the size of single piece of predicate device is 94×26mm. Every size of propose device is designed according to ASTM E XX and the result is qualified. All sizes of proposed device are safe and effective.）***

***（参考示例2：The size of single piece of proposed device is varied size. While the size of single piece of predicate device is 94×26mm. The different size just shows different appearance. It meets the requirements of the clinical use. At the same time, all size of the product meets the requirements of product specification and product standard. All sizes of proposed device are safe and effective.）***

***So this difference does not affect the effectiveness and safety of our device.***

(2) Different 2: ***{填写对比项}***

***{填写差异不影响产品安全有效的说明 }***

So this difference does not affect the effectiveness and safety of our device.

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1. **Non-Clinical Performance Data**

*Biocompatibility Tests*

The ***{填写器械名称}*** has been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

* ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity.
* ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin sensitization.

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***【生物相容性涉及的标准，需要结合产品实际情况，根据ISO 10993-1进行判断，并得出具体需要测试的项目，并按照相应的产品进行测试，同时需要考虑指南***

***“Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.”的要求。】***

*Performance Tests*

 ***{填写器械涉及标准 }***

Conclusion: The ***{填写器械名称}*** have demonstrated the product has same intended use and similar technological characteristics as that of the predicate device. Performance testing showed it performs in a manner that is substantially equivalent to the legally marketed predicate device.

1. **Substantial Equivalent Conclusions**

***{填写器械名称}*** has the same intended use, similar technological characteristics as the predicate device. Moreover, non-clinical testing contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness.

In conclusion, ***{填写器械名称}*** is substantial equivalent to the predicate device.