**Executive Summary**

1. **Submitter's Identification:**

|  |  |
| --- | --- |
| Owner’s Name: | ***{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）*** |
| Phone: | ***{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 }*** |
| Contact: | ***{填写联系人英文名称 }*** |

1. **Name of the device:**

· **Trade/Proprietary 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}***

· **Classification :** II

· **Product Code: *{填写产品代码 }***

1. **Device Description:**

***{填写产品描述 }***

**4. Difference**

The following table specifically describes the differences between each model of ***{填写器械名称，及所有型号}。***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | **........** | **........** | **........** | **........** | **........** |

**5. Indication for Use**

***{填写产品适应症 }***

**6. Technological Characteristics of Device as to Compare to the Predicate Device**

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |
| Intended  Use | ***{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 |
| ..... |  |  |  |

**7. Comparison Summary**

**7.1** **Discussion of Similarities and Differences**

The features of the ***{填写器械名称}*** are compared to predicate devices in the form of above tables.

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.

........

**7.2 Argument for Substantial Equivalence to Predicate Devices:**

All above is the comparison between ***{填写器械名称}*** and legally marketed device, which shows the proposed device and the Predicate Device are substantially equivalent.

**8. Biocompatibility**

The ***{填写器械名称}*** have 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.

1. **Summary of non-clinical performance Tests**

* ***{填写器械涉及标准}***

**10. Conclusion**

From the comparison above, we have demonstrated that there are no significant differences between each model and ***{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.