**Substantial Equivalence Discussion**

1. **Purpose**

The following is a comparison between the ***{填写器械名称}*** (Subject Device) and legally marketed device. The result shows the conformance of Subject Device to the Predicate Devices.

1. **Predicate Devices**

Subject Device is substantially equivalent in its technologies and functionality to the ***{填写对比器械名称}*** manufactured by ***{填写对比器械制造商}*** that is already cleared under premarketed notification number ***{填写对比器械K号}***.

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

**3. Comparison Result**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** |  **Proposed Device** | **Predicate Devices**  | **S/D** |
| 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 |
| ..... |  |  |  |

**Note:** S/D: Same/Different

**4.** **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.

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**5. Conclusion**

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 is substantially equivalent.