**Performance Testing \_Bench**

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**1. Summary**

This 510(k) submission submits bench test results to support substantial equivalence and maintains performance testing report of the devices. The types of test,and the test results are summarized as follows. The test results demonstrate that the proposed device met its performance specifications.

1.1 Performance Test

The performance bench testing of ***{填写申报产品名称 }*** (model: ***{填写申报产品的具体型号}***) include the following:

|  |  |  |
| --- | --- | --- |
| **Test item** | **Test Standards** | **Result** |
| ***{填写测试项目}*** | ***{填写测试项目对应的标准 }*** | Pass |
| ***{填写测试项目}*** | ***{填写测试项目对应的标准 }*** | Pass |
| ***.....*** | ***.....*** | Pass |

1.2 Full test report of all completed test

|  |  |  |
| --- | --- | --- |
| **Test Report** | **Test Standards** | **Remark** |
| ***{填写文档中测试报告名}***  ***(参考示例：IEC 60601-1***  ***Test Report)*** | ***{填写测试项目对应的标准 }***  ***(参考示例：IEC 60601-1 )*** | Report No.:  ***{填写测试报告编号}*** |
| ***{填写文档中测试报告名}***  ***(参考示例：IEC 60601-1***  ***Test Report)*** | ***{填写测试项目对应的标准 }***  ***(参考示例：IEC 60601-1 )*** | Report No.:  ***{填写测试报告编号}*** |
| ***.....*** | ***.....*** | ***.....*** |

**2. Explanation of the data from test report supports Substantial equivalence**

***{填写解释从每个测试中产生的数据如何支持实质等同}***

***(参考示例：***

***Both the {填写申报产品名称 } (model: {填写申报产品的具体型号}) and the predicate device have the same intended use and similar technological characteristics, {填写产品预期用途}. Compare with the subject device and predicate device(the detailed comparison table can be referred to “Substantial Equivalence Discussion)”, the subject device has same intended use, similar product design, same performance effectiveness, and performance safety as the predicate device.***

***The differences between the subject device and predicate device are minor and both***

***products meet the same standard {填写产品专标}, ISO 10993-5 and ISO 10993-10. The differences between the subject device and predicate device do not affect the intended use, product design, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety. Thus, the subject device is substantially equivalent to the predicate device.***

***The detailed comparison table and discussion of differences between subject and***

***predicate can be referred to “Substantial Equivalence Discussion”.***

***)***