**Reference to previous generations of the device and to similar devices**

**Product Name:*****{填写申报产品名称 }***

**Model:*{填写申报产品的具体型号}***

**Document No.: *{填写本文档编号}***

**Edition: *{填写本文档版本号}***

Drafted by: Date: ***{填写本文档编写日期}***

Checked by: Date: ***{填写本文档审核日期}***

Approved by: Date: ***{填写本文档批准日期}***

***{填写申请者的企业名称}（参考示例：Shenzhen Hlongmed Biotech Co.,Ltd.）***

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Approved by** | **Checked by** | **Drafted by** |
| *{填写具体的版本号}* | *{填写对应版本的有效日期}* | *{对版本进行简要描述}* | *{填写文件批准人姓名}（参考示例：San Zhang）* | *{填写文件审核人姓名}（参考示例：Si Li）* | *{填写文件起草人姓名}（参考示例：Wu wang）* |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist**

*{若申报产品有前代产品的话，请对前代产品进行简要概述}【参考示例：The actual device is the First-generation products, we consider there is no previous generation 】*

**2. An overview of identified similar devices available on the Union or international markets, where such devices exist.**

*{对欧盟以及国际市场上的类似产品进行简要概述}*