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

Submission type: Traditional 510(k)

Trade/Device 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}***

Submission language: English

According to the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, September 13, 2019, the submission includes the sections in the sequence below:

| **Section** | **Title** | **Page** | **Mark** |
| --- | --- | --- | --- |
| 1 | Table of Contents  | ***{填写文件页码}（参考示例：1-1~1-38.）*** |  |
| 2 | Medical Device User Fee Cover Sheet(Form FDA 3601) | ***{填写文件页码}*** |  |
| 3 | CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) | ***{填写文件页码}*** |  |
| 4 | 510(k) Cover Letter | ***{填写文件页码}*** |  |
| 5 | Indications for Use Statement(Form FDA 3881) | ***{填写文件页码}*** |  |
| 6 | 510(k) Summary | ***{填写文件页码}*** |  |
| 7 | Truthful and Accuracy Statement | ***{填写文件页码}*** |  |
| 8 | Class III Summary and Certification | ***{填写文件页码}*** | N/A |
| 9 | Financial Certification or Disclosure Statement | ***{填写文件页码}*** | N/A |
| 10 | Declarations of Conformity and Summary Reports | ***{填写文件页码}*** | N/A |
| 11 | Device Description  | ***{填写文件页码}*** |  |
| 12 | Executive Summary Predicate Comparison | ***{填写文件页码}*** |  |
| 13 | Substantial Equivalence Discussion | ***{填写文件页码}*** |  |
| 14 | Proposed Labeling | ***{填写文件页码}*** |  |
| 15 | Sterilization and Shelf Life | ***{填写文件页码}*** |  |
| 16 | Biocompatibility  | ***{填写文件页码}*** |  |
| 17 | Software | ***{填写文件页码}*** | N/A |
| 18 | Electromagnetic Compatibility and Electrical Safety | ***{填写文件页码}*** | N/A |
| 19 | Performance Testing\_Bench | ***{填写文件页码}*** |  |
| 20 | Performance Testing\_Animal | ***{填写文件页码}*** | N/A |
| 21 | Performance Testing\_Clinical | ***{填写文件页码}*** | N/A |
| 22 | Test Report | ***{填写文件页码}*** |  |

According to the “ Refuse to Accept Policy for 510(k)s -Guidance for Industry and Food and Drug Administration Staff , September 13, 2019” , we included the “Acceptance Checklist for Traditional 510(k)s” in the Appendix A.