序号	Title	文件名	Related Information
1	Medical Device User Fee Cover Sheet(Form FDA 3601)	缴费证明文件	Medical Device User Fee Cover Sheet
2	CDRH Premarket Review Submission Cover Sheet	CDRH上市前审核提交表格	CDRH Premarket Review Submission Cover Sheet
3	510(k) Cover Letter	510k封面信件	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s"
4	Indications for Use Statement	预期用途	Indications for Use Statement
5	510(k) Summary or 510(k) Statement	510k总结或510k声明	510(k) Summary or 510(k) Statement
6	Truthful and Accuracy Statement	真实与准确性声明	Truthful and Accuracy Statement
7	Class III Summary and Certification	III类总结和声明	III类设备所需准备的
8	Financial Certification or Disclosure Statement	财务证明或应行公告的财务事项	Certification Disclosure
9	Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	一致性声明和总结报告（简要510k）	该文件适合510k提交方式为简要510k
10	Executive Summary	执行总结	
11	Device Description	设备说明	
12	Substantial Equivalence Discussion	实质性等同描述	Substantial Equivalence Discussion
13	Proposed Labeling	标签	Labeling
14	Sterilization and Shelf Life	灭菌和货架寿命	无菌产品参照Sterilization 再造重新使用产品参照reprocessed single-use
15	Biocompatibility	生物相容性	Biocompatibility
16	Software	软件	Software
17	Electromagnetic Compatibility/Electrical Safety	电磁兼容和电气安全	
18	Performance Testing - Bench	性能测试报告	
19	Performance Testing - Animal	动物实验报告	
20	Performance Testing-Clinical	临床试验资料	
21	FORM FDA 3654,Standards Data Report for 510(k)s	适用标准	Standards Data Report Form-Form 3654

备注：本清单为产品510K提交形式为“传统”（510k提交方式：传统、特殊和简要-传统适用范围广、特殊为已有产品的更改、简要为产品有明确的Guidance,我们的产品可以选择“传统”）时所需文件，如为特殊（非提交形式中的“特殊”）产品还需结合Guidance Documents指导文件下的要求。