eSTAR 510k Sections

1. Cover Letter / Letters of Reference
2. Applicant Information
3. Pre-Submission Correspondence & Previous Regulator Interaction
4. Standards
5. Device Description
    - Listing of Device
    - Device Description Summary
    - System/Kit Components and accessories
6. Indications for Use Form
7. Classification
8. Predicates and Substantial Equivalence
9. Labeling
    - Package Labeling
    - Package Insert/IFU
    - Other Labeling
10. Reprocessing, Sterility, and Shelf-Life
    - Reprocessing, Sterility, and Shelf-Life Documents
11. Biocompatibility
    - Biocompatibility Reports and Documentation
12. Software/Firmware Cybersecurity/Interoperability:
    - Software / Firmware / Programmed or Programmable Medical Device

    - Documentation Level Evaluation (Basic or Enhanced)
    - Software / Firmware Description
    - Risk Management File (including Hazard Analysis)
    - Software Requirements Specifications (SRS)
    - System and Software Architecture Design (SAD) Chart
    - Software Design Specifications (SDS) (Applicable for Enhanced Documentation)
    - Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices
    - Software Testing as Part of Verification & Validation
    - Software Version / Revision Level History
    - Unresolved Software Anomalies
- Cybersecurity
    - Risk Management - Report
    - Risk Management - Threat Model
    - Risk Management - Cyber Security Risk Assessment
    - Risk Management - Software Bill of Materials (SBOM) and Related Information
    - Assessment of Unresolved Anomalies
    - Cybersecurity Metrics
    - Cybersecurity Controls
    - Architecture Views
    - Cybersecurity Testing
    - Cybersecurity Labeling
    - Cybersecurity Management Plan
- Interoperability

13. EMC, Wireless, Electrical. Mechanical, and Thermal Safety

- EMC, Wireless, & EMT Documentation

14. Performance Testing
    - Bench Testing
    - Animal Testing
    - Clinical Testing
15. References
16. Administrative Documentation
    - General Summary of Submission/Executive Summary
    - Truthful and Accurate Statement
    - 510(k) Summary or Statement
    - User Fee Form
17. Verification

Templates for 510k

1. **Substantial Equivalence Table**

Parameters	Subject Device	Predicate Device	Comparison. (If different, provide a rationale that it won't raise any questions of safety and effectiveness)

Add a extra column or create a new table if you have secondary or reference device

2. **Biocompatibility Reports**

Test Name and ISO standard	Study No	Observation	Test Result
ISO 10993-5 Cytotoxicity			

3. **Software Requirement Specification**

SRS ID	Category	Requirement Description

4. **Software Testing - Verification and Validation**

Test Case ID	Test Case Description	Test Steps	Expected Result	Actual Result	Pass or Fail Determination

5. **Software Version History**

Date of version	Version Number	Testing Level (Unit/Integration/ System)	Testing Type	Description of Changes	Impact on Safety & Effectiveness

6. **Unresolved Software Anomaly**

Anomaly ID	Description of Anomaly	Root Cause of Anomaly	Identification of Anomaly	Impact on Safety & Effectiveness	Evaluation Outcome	Risk-Based Rationale for Not Fixing

7. **SBOM (Software Bill of Materials)**

Software Component Name	Description of the Component	Software Package / Library	Software Type	Version	Manufacturer	License	Vulnerability

In addition to above table, FDA recommend to provide information on:

Dependency	Level of Support	End-of-support date

8. **OTS Software (Off the Shelf)**

OTS Software Name	Manufacturer	Version Number	Purpose	Appropriateness of the OTS Software for the Medical Device	Hardware / Software Specifications	Expected design limitations of the OTS software

9. **Risk Assessment**

Risk ID	Hazard Category	Hazard	Hazardous Situation	Harm	Initial Severity	Initial Occurrence	Initial Risk

Risk Control	Risk Mitigation	Risk Traceability	Residual Severity	Residual Occurrence	Residual RPN	Risk and Benefit Analysis

10. Cybersecurity

11. EMC Testing

Note: When do you create the software documents??

Software Documentation Requirements	**When to Start Documentation??**
Documentation Level Evaluation	Before Coding
Software / Firmware Description	Before Coding
Risk Management File (including Hazard Analysis)	Before and after Coding
Software Requirements Specifications (SRS)	Before Coding
System and Software Architecture Design (SAD) Chart	Before Coding
Software Design Specifications (SDS) (Applicable for Enhanced Documentation)	During Coding
Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices	Iterative Process
Software Testing as Part of Verification & Validation	After Coding
Software Version / Revision Level History	After Coding
Unresolved Software Anomalies	After Coding