

HOW TO AUTOMATE COMPLIANCE CHECKLISTS FOR 510(k) SUBMISSIONS USING AI

The Ultimate FDA 510(k) Submission Checklist 2025 Edition

*Comprehensive Guide to FDA 510(k) Requirements
Ensure RTA Compliance and Avoid Submission Delays*

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Learn how to automate compliance checklists for 510(k) submissions using AI-powered tools. This comprehensive guide covers all 19 major sections required for a complete FDA 510(k) submission, including administrative forms, technical documentation, testing requirements, and specialized sections for software, cybersecurity, biocompatibility, and more.

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SECTION 1: ADMINISTRATIVE & COVER DOCUMENTS

This section ensures your submission is properly identified and routed.

Get this wrong, and the FDA won't even begin the review.

- Medical Device User Fee Cover Sheet (Form FDA 3601)**
Proof of payment for the 510(k) review fee. This is the very first thing they check.
- CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)**
Contains essential information about your company, device, and submission type.
- 510(k) Cover Letter**
A formal letter identifying the submission type, device name, and primary contact person.
- Table of Contents**
A clear, paginated guide to the entire submission. The eSTAR template generates this automatically.
- Indications for Use Statement (Form FDA 3881)**
A precise, one-paragraph statement defining the intended use of your device.
- Truthful and Accuracy Statement**
A legally binding declaration that all information provided is truthful and accurate.

SECTION 2: DEVICE DESCRIPTION & PREDICATE COMPARISON

This is the core of your submission, where you build the argument for Substantial Equivalence (SE).

- Comprehensive Device Description**
Detail the device's design, components, materials, principles of operation, and technical specifications.
- Predicate Device Identification**
Clearly state the 510(k) number(s) for your chosen primary and (if applicable) secondary predicate devices.
- Substantial Equivalence Comparison Table**
A side-by-side table comparing your device to the predicate(s) across key characteristics.
- Executive Summary / SE Narrative**
A summary that explains why the differences between your device and the predicate do not raise new questions.

SECTION 3: LABELING & STERILIZATION

- Draft Labeling**
Includes device labels, Instructions for Use (IFU), and any patient labeling.

- Sterilization and Shelf Life (if applicable)**
Full details of the sterilization method, validation protocols, and shelf life data.

- Biocompatibility (if applicable)**
A declaration of conformity to ISO 10993 and summary of biocompatibility testing.

SECTION 4: SOFTWARE DOCUMENTATION (IEC 62304)

For devices with software functionality, comprehensive software lifecycle documentation is required.

- Software Safety Classification & Rationale**
Determine the Level of Concern (A, B, or C) and justify the classification.

- Software Architecture & Design (SDS/SDD)**
Detailed software design specification including architecture diagrams and modules.

- Software Verification & Validation Summary**
Complete V&V protocols, test results, and evidence of software quality assurance.

- SOUP / OTS & Cyber-Related Components List**
Software of Unknown Provenance and Off-The-Shelf components inventory.

- Maintenance & Configuration Management**
Procedures for software updates, version control, and configuration management.

SECTION 5: CYBERSECURITY DOCUMENTATION

Critical for connected devices, software-controlled devices, or any device with network interfaces.

- Threat Modeling & Security Risk Assessment**
Comprehensive threat enumeration, attack vectors, and security risk analysis.
- SBOM (Software Bill of Materials)**
Complete inventory of all software components, versions, and dependencies.
- Vulnerability Management & Patching Policy**
Procedures for identifying, assessing, and addressing security vulnerabilities.
- Access Control, Authentication & Logging**
Security controls for user access, authentication mechanisms, and audit logging.

SECTION 6: BENCH & PERFORMANCE TESTING

Provide objective, scientific evidence that your device performs as intended and is safe for use.

- Bench Test Summary & Acceptance Criteria**
Overview of all performance testing with clear acceptance criteria.
- Performance Test Reports**
Detailed protocols and results for all non-clinical tests supporting device performance claims.
- Environmental/Stress Tests**
Testing under various environmental conditions and stress scenarios.
- Precision/Repeatability Testing**
Evidence of device precision, accuracy, and repeatability under normal use conditions.
- Interoperability Testing (if applicable)**
Testing with external systems, devices, or software platforms.

SECTION 7: ELECTRICAL SAFETY & EMC

Required for all electrically powered or active devices.

- Electrical Safety (IEC 60601-1)**
Complete electrical safety testing including test matrix, results, and deviations.

- EMC (IEC 60601-1-2)**
Electromagnetic compatibility testing including emission and immunity testing.

SECTION 8: BIOCOMPATIBILITY (ISO 10993)

Required for any device with patient-contacting materials.

Biocompatibility Evaluation & Justification

Complete evaluation following ISO 10993-1 matrix based on contact type and duration.

Biocompatibility Test Reports

Cytotoxicity, sensitization, irritation/intracutaneous reactivity, and other applicable tests.

SECTION 9: STERILIZATION & MICROBIOLOGY

Required for devices supplied sterile.

- Sterilization Method & SAL**
Detailed sterilization process including cycle parameters and Sterility Assurance Level.
- Sterilization Validation Reports**
Complete validation studies demonstrating sterilization effectiveness.
- Packaging Sterile Barrier**
Validation of packaging integrity and sterile barrier maintenance.
- Pyrogen/Endotoxin Testing**
Testing for pyrogenic substances as applicable to the device.
- Residuals / EO Aeration (if EO sterilized)**
Testing for ethylene oxide residuals and aeration validation.

SECTION 10: REPROCESSING / CLEANING / DISINFECTION

Required for reusable devices that require cleaning and disinfection.

Reprocessing Instructions

Detailed instructions for use including soil selection, worst-case loads, and acceptance criteria.

Reprocessing Validation

Validation studies demonstrating effective cleaning and disinfection.

SECTION 11: PACKAGING INTEGRITY & SHELF LIFE

Required for devices with sterile packaging or labeled shelf life.

Packaging Integrity Validation

Seal strength testing, transit/drop testing, and distribution robustness validation.

Shelf Life Testing

Aging protocols and results supporting claimed shelf life for sterile and non-sterile devices.

SECTION 12: CLINICAL PERFORMANCE (if applicable)

Required when clinical data is needed to support substantial equivalence.

Clinical Rationale for SE

Study design, endpoints & statistics, and risk/benefit narrative.

Clinical Study Reports / Literature

Complete clinical study reports or literature review supporting safety and effectiveness.

SECTION 13: HUMAN FACTORS & USABILITY

Required for devices with use-related risks, home use, or pediatric use.

- HFE/UE Plan**
Human factors engineering plan including use-error analysis (URRA/UFMEA).
- Formative Study Rounds**
Iterative usability testing to identify and resolve use-related issues.
- Summative (Validation) Study Report**
Final validation study demonstrating safe and effective use.

SECTION 14: INTEROPERABILITY

Required for devices that interoperate with external systems.

Interoperability Description & Standards

Profiles/standards (HL7/FHIR/IEEE) and negative tests/failure modes.

Interoperability Testing Evidence

Testing results demonstrating successful interoperability with external systems.

SECTION 15: RADIATION SAFETY / EMISSIONS

Required for devices that emit radiation.

Radiation Emission Safety

Safety evaluation and testing for devices that emit radiation (per 21 CFR 1000-1050).

SECTION 16: WIRELESS / RF COMPLIANCE

Required for devices with wireless functionality.

RF Compliance (FCC/ETSI test reports)

Radio frequency compliance testing and certification for wireless devices.

SECTION 17: MRI SAFETY (IMPLANTABLE DEVICES)

Required for implantable devices or devices labeled as MR Conditional.

MRI Safety Evaluation

Testing per ASTM F2503 and other applicable standards for MRI compatibility.

SECTION 18: STANDARDS & DECLARATIONS OF CONFORMITY

Required for all devices - comprehensive standards compliance documentation.

Standards Applicable Table

Complete conformity matrix showing applicable standards and compliance status.

Deviations & Rationales

Any deviations from standards with detailed justifications.

Declarations of Conformity

Formal declarations of conformity to applicable standards.

SECTION 19: SUPPORTING DOCUMENTS

Additional documentation that supports the submission.

- Requirements Traceability Matrix**
Traceability from requirements through testing to evidence (for software and performance-critical devices).

- Photos / Drawings / Schematics**
Device photos, engineering drawings, and technical schematics.

- UDI/UDID (if applicable)**
Unique Device Identifier and Universal Device Identification Database information.

IMPORTANT TIPS FOR SUCCESS

- Use the eSTAR template for all submissions (required as of October 1, 2023)
- Ensure all forms are completed accurately and signed
- Double-check that your predicate device(s) are still legally marketed
- Include all required test reports with proper signatures and dates
- Verify that your device description matches your labeling exactly
- Submit all documents in the correct eSTAR format
- Include a comprehensive table of contents
- Ensure all required fees are paid before submission

Need Help?

Cruxi AI can help automate your 510(k) submission process:

- AI-powered document generation
- Automated eSTAR compliance checking
- Real-time RTA deficiency prevention
- Comprehensive evidence planning

Visit <https://cruxi.ai> to learn more

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