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RTA Prevention Checklist 2026

12 critical checkpoints

Apply the 4-Axis method before submission.

Catch what the FDA catches first.

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v1.0 - 2026

Why this checklist exists

The Refuse to Accept (RTA) policy is FDA's first filter on your 510(k). A submission rejected at RTA loses 30 to 60 days before substantive review even begins. Most RTAs trace back to preventable clarity gaps, not science.

This checklist walks you through the 12 most common ones, organized by the 4-axis methodology used in every Martinez Clarity audit. Use it as the last pass before submission, or as a self-diagnostic on a draft in progress.

For each item : check the box if your draft meets the criterion. If not, apply the action stated.

AXIS 1 — TERMINOLOGY CONSISTENCY

1.1 Device Name Is the device name exactly identical (capitalization, punctuation, spacing) across the Cover Letter, 510(k) Summary, Indications for Use, and Form 3514 ?

☐ Yes ☐ No

Action : Standardize to a single canonical name. Run a find-and-replace pass across all documents

1.2 Predicate Name Is the predicate device name written identically at every occurrence in the Summary and the comparison table, including the predicate K-number ?

☐ Yes ☐ No

Action : Choose one canonical format (manufacturer + device name + K-number) and apply globally.

1.3 Component and Accessory Terms Are all components, accessories, and software modules named consistently throughout the dossier ?

☐ Yes ☐ No

Action : Build a terminology map before submission. One column per term, one column per accepted form.

AXIS 2 — REQUIREMENTS-TO-TESTS TRACEABILITY

2.1 Performance Claims Anchored For every performance claim in the 510(k) Summary, is a specific test method, recognized standard, and quantified result explicitly cited ?

☐ Yes ☐ No

Action : Add missing references. No claim of "similar performance" survives without data.

2.2 Predicate Comparison Table Does every "similar" or "equivalent" cell in the predicate comparison table have a supporting footnote referencing a specification, standard, or test report ?

☐ Yes ☐ No

Action : Anchor every similarity to a numbered specification, named standard, or referenced test report.

2.3 Risk-to-Verification Trace Is the ISO 14971:2019 risk management file explicitly cross-referenced with verification test reports in the submission ?

☐ Yes ☐ No

Action : Ensure each identified risk traces to a test that verifies the mitigation. The trace must be visible in the dossier, not just in your internal files.

AXIS 3 — RTA ACCEPTANCE CHECKLIST ALIGNMENT

3.1 Form 3514 vs Cover Letter Do the device name, classification, product code, and applicant details on Form 3514 match the Cover Letter exactly ?

☐ Yes ☐ No

Action : Cross-check both documents side by side before submission. A single mismatch triggers an RTA flag.

3.2 Table of Contents Accuracy Does the Table of Contents reflect the final document structure and actual page numbers ?

☐ Yes ☐ No

Action : Update the Table of Contents after all edits are locked. Never submit with a draft ToC.

3.3 Substantial Equivalence Conclusion Does the 510(k) Summary contain an explicit, clearly identifiable conclusion of Substantial Equivalence per 21 CFR 807.92(a)(3) ?

☐ Yes ☐ No

Action : Add a dedicated paragraph stating the SE conclusion and referencing the predicate K-number.

AXIS 4 — DEVICE-SPECIFIC COMPLIANCE (2026 CONTEXT)

4.1 Software / SaMD (if applicable) a. Documentation Level declared (Basic or Enhanced) per FDA "Content of Premarket Submissions for Device Software Functions" (June 2023) ? b. IEC 62304 compliance with software safety classification (Class A, B, or C) ? c. SBOM present and traceable to the cybersecurity summary and risk management file ?

☐ Yes ☐ No ☐ N/A

Action : Cross-check Documentation Level against risk assessment outcome. SBOM must align with the cybersecurity summary AND risk management file. All three must reconcile.

4.2 AI/ML Devices (if applicable) PCCP included for adaptive algorithms, per FDA "Marketing Submission Recommendations for a Predetermined Change Control Plan" (September 2024 final) ? b. Algorithm validation across multiple geographically and demographically diverse sites, with explicit justification of dataset representativeness for the US patient population per FDA "Good Machine Learning Practice for Medical Device Development" (October 2021) ?

☐ Yes ☐ No ☐ N/A

Action : Document dataset composition explicitly. Justify generalization to the US population in narrative form, not just numerical tables.

4.3 Validation Data Demographics. Does the validation data reflect the intended US patient population (not primarily European or single-site data) ?

☐ Yes ☐ No ☐ N/A

Action : Justify dataset composition explicitly, or supplement with additional sites before submission.

QUICK SCORING

Count each numbered item as one check. For 4.1 and 4.2, all sub-items must be Yes for the full item to count.

12 / 12 — Strong baseline. Your draft passes the clarity checks. A full audit can still surface deeper structural issues.

9 to 11 / 12 — Fix gaps before submission. Each missing item is a likely AI request trigger.

Below 9 / 12 — High RTA risk. Do not submit without a thorough clarity review.

WHAT'S NEXT

If you scored 9 to 11, your draft is close. The fixes are usually small and structural, not scientific. You can run them yourself in 2 to 3 days.

If you scored below 9, the gaps go deeper than this checklist captures. A 5-day clarity audit will surface what this PDF cannot : terminology drift across non-checked sections, predicate comparison weak points, cybersecurity section depth, traceability gaps that only show up under careful reading.

Apply for a free clarity audit at martinezclarity.com Currently offering 3 free audits to QA/RA leads with a submission in the next 90 days.

About Martinez Clarity

Martinez **Clarity** is an independent clarity review service for 510(k) submissions, founded by Rémy Martinez in early 2026.

The service reviews 510(k) drafts for clarity, terminology consistency, and traceability gaps before submission to the FDA. It does not provide regulatory strategy, study design, or legal advice.

Current offer (June to July 2026) 3 free clarity audits, available to QA/RA leads with a 510(k) submission planned in the next 90 days. No catch, no future invoice. Applicants receive a 15 to 20 page PDF report on day 5, followed by a 30-minute walkthrough.

Public work 3 audits of cleared 510(k)s published independently, available at martinezclarity.com. No client relationship, no compensation. The methodology, applied in the open.

Apply or learn more at martinezclarity.com

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Based on FDA Refuse to Accept Policy for 510(k)s (2019, current operative version) and observed RTA patterns 2024 to 2026. For internal preparation use. Does not constitute regulatory consulting or legal advice. Does not replace a full pre-submission audit.