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Public 510(k) Clarity Audit - K241101

BioButton System (Wireless Remote Patient Monitoring)

Applicant : BioIntelliSense,
Inc. FDA Decision Date : September 26, 2024.
Audit Date: June 4, 2026.
Audit #2 of the Public Clarity Audit series.

Source document : FDA 510(k) database, K241101. Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241101

Independent review notice. This audit relies exclusively on the public 510(k) Summary documents released by the FDA for K241101. Martinez Clarity has no affiliation with the manufacturer. This audit is published for educational and methodology demonstration purposes only. The audited submission was successfully cleared by the FDA in September 2024. The findings below represent observations of documentary clarity. They are not regulatory deficiencies, and they do not call into question the cleared status of the device.

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Executive Summary

This audit applies the Martinez Clarity 4-Axis methodology to the public 510(k) Summary of the BioButton System (K241101).

8 findings were identified:

- 4 Red: Likely to trigger a Refuse to Accept (RTA) hold or an Additional Information (AI) request letter under current 2026 review conditions.
- 4 Yellow: Likely to slow review under current reviewer bandwidth constraints.
- 0 Green: Cosmetic, no impact on review.

This submission was cleared by the FDA in September 2024. Under the review conditions of that period, none of these gaps were blocking. Today, however, with the tightening of acceptance criteria, stricter application of the June 2023 software guidance, the mandatory SBOM requirement from June 2025, and reviewer workforce reduction at CDRH, similar documentary gaps systematically trigger AI request letters on submissions currently under review. The typical added delay is 45 to 60 days.

The most notable structural pattern in this submission is the combination of two findings: a major technological transition (single-use to multiple-use) justified in a single word, and the unannounced introduction of a second reference device directly inside the performance comparison tables.

Axis	**Findings**	**Highest severity**
1. Terminology Consistency	2	Yellow
2. Requirements to Tests Traceability	1	Red
3. RTA Acceptance Checklist Alignment	2	Red

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Axis	Findings	Highest severity
4. Device-Specific Compliance	3	Red

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Methodology

This audit follows the Martinez Clarity 4-Axis methodology.

Axis 1. Terminology Consistency. Verification of device names, predicate names, components, and technical terms across all sections. Drift signals either a rushed submission or a multi-author draft without a final harmonization pass.

Axis 2. Requirements to Tests Traceability. Verification that every performance claim and risk statement is anchored to a named test protocol, a recognized standard, and a quantified result. Unanchored claims invite reviewer clarification requests.

Axis 3. RTA Acceptance Checklist Alignment. Verification of the public-visible elements of the FDA Refuse to Accept Policy for 510(k)s: complete predicate identification, alignment of indications for use, and the rigor of the substantial equivalence conclusion.

Axis 4. Device-Specific Compliance (Wearables and Connected Hardware, 2026 context): validation of battery lifecycle protocols, reprocessing declarations for multi-patient use, traceability of biocompatibility standard versions (ISO 10993), electrical safety (IEC 60601 family), Documentation Level under the June 2023 software guidance, and cybersecurity controls including SBOM (mandatory since June 2025).

Severity scale:

- Red: High likelihood of RTA hold or immediate AI request under current FDA review conditions.
- Yellow: Likely to slow review, generate secondary clarification questions.
- Green: Cosmetic gap, no impact on the decision.

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Findings

AXIS 1, TERMINOLOGY CONSISTENCY

Finding 1 — Truncated device name in document headers [Yellow]

Axis : Terminology Consistency Page reference: 510(k) Summary, recurring headers on pages 1 to 8

Cited text :

"BioButton 510(k) Summary" (page headers, pages 1 to 8)

Risk analysis. The official trade name validated by the FDA is "BioButton System", as declared on the cover page and in Section II. The page headers consistently truncate this designation, omitting the word “System”. In a connected health submission that combines a physical sensor, a mobile gateway, and cloud components, terminology uniformity across all running headers is expected. The truncation introduces a minor ambiguity over whether the Summary covers the sensor component alone or the full system configuration.

Recommended fix. Standardize all document headers using the complete trade name: "BioButton System 510(k) Summary".

Finding 2 — "Patient" versus "User" drift across IFU, Summary text, and comparison table [Yellow]
Axis: Terminology Consistency Page references: Indications for Use (FDA form), 510(k) Summary Section V (page 3), Comparison Table Section VI (pages 3-4)

Cited text :

"The Device is intended for use on patients who are 18 years of age or older." (Indications for Use) "The device is intended for use on users who are 18 years of age or older." (Section

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V, page 3) Subject Device column : Patient / Predicate Device column : User (Comparison Table, page 4)

Risk analysis. Under FDA practice, Patient implies an individual under active medical supervision within a defined clinical workflow. User can be read as a general consumer in a wellness context. Switching between the two terms across the IFU, the narrative text of Section V, and the columns of the comparison table introduces uncertainty over the intended population. Under current review climate, a reviewer is likely to issue a clarification request to confirm the boundaries of the prescription-only (Rx) indication, particularly given that the device is marketed as Prescription Use only.

Recommended fix. Align all narrative content with the canonical IFU language. Replace User with patients throughout Section V and harmonize the comparison table so that both Subject and Predicate columns use the same term.

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AXIS 2, REQUIREMENTS TO TESTS TRACEABILITY

Finding 3 — ISO 14971 absent from the Safety standards matrix [Yellow]

Axis 2: Requirements to Tests Traceability Page reference: 510(k) Summary, Section VI Safety table (page 6)

Cited text. The Safety standards matrix lists IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, and ISO 10993-1. ISO 14971 is not listed in the matrix.

Risk analysis. ISO 14971 governs the risk management process, not a product compliance category like IEC 60601. Its absence from the Safety standards matrix is therefore not a regulatory violation in itself. However, in current 2026 review practice, the absence of ISO 14971 compliance creates a blind spot for the reviewer assessing the structural completeness of the file. The Summary text references risk management in the Cybersecurity section but does not formally attach this process to ISO 14971.

Recommended fix. Add a dedicated row or a separate compliance declaration for ISO 14971:2019 within the standards matrix or in a Risk Management section, with cross-references to verification test reports.

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AXIS 3, RTA ACCEPTANCE CHECKLIST ALIGNMENT

Finding 4 — Performance comparison anchrored to an undeclared third device [Red]

Axis : RTA Acceptance Checklist Alignment Page references: Section III (page 2), Section III.A (page 2), Section VI (page 6)

Cited text :

> Section III declares: "Predicate Device Trade Name : BioButton System (K212957)" Section III.A declares two Reference Devices : Vios Monitoring System (K172586) and Vivify Health Care Team Portal (K222398) The Performance comparison table on page 6 compares the Subject Device against: "BioSticker System (K191614)"

Risk analysis. The Performance comparison table presents heart rate range, respiratory rate range, and skin temperature accuracy data against the BioSticker System (K191614). This device is the BioIntelliSense predecessor product line, but it is declared neither as the predicate (Section III declares K212957) nor as a Reference Device (Section III.A declares K172586 and K222398). The reader is left to assume the comparison basis without explicit declaration. A reviewer or an automated FDA analysis tool will flag this as an unanchored comparison and will request justification for the implicit substitution of the comparison basis. Under current review climate, this is a likely RTA hold trigger.

Recommended fix. Formally declare BioSticker System (K191614) as a Reference Device in Section III.A. Add a one-sentence transition before the Performance table explaining why BioSticker (K191614) is used as the performance baseline instead of the declared Predicate (K212957). Alternatively, repeat the Performance comparison data against the declared Predicate.

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Finding 5 — Major design transition from Single-use to Multiple-use justified in one word [Red]

Axis 3: RTA Acceptance Checklist Alignment Page reference: 510(k) Summary, Comparison Table (page 5)

Cited text :

Single-use / Multiple-use row : Subject Device : "Multiple-use" / Predicate : "Single-use" / Justification of Difference : "**Different**"

Risk analysis. Moving from a single-use patch to a reusable enclosure introduces new risk vectors: battery degradation over multiple cycles, mechanical wear of the enclosure, and cross-contamination between patients. A single-word "Different" in the justification column fails the substantial equivalence demonstration because it does not explain why these new risk vectors do not raise new questions of safety and effectiveness, as required by 21 CFR 807.92(a)(3).

A second internal inconsistency reinforces this finding: the same comparison table reports Re-processing between each use? No for both the Subject and Predicate devices, while Section VI (page 7) states "Cleaning validation — testing validates cleaning and disinfection instructions for multiple-patient use." The document therefore declares no reprocessing in one section and validates reprocessing instructions in another.

Recommended fix. Expand the Justification of Difference column with a synthetic summary of the verification testing supporting the multiple-use design: enclosure durability test references, battery cycle life testing references, biocompatibility retesting after cleaning cycles. Reconcile the "Re-processing : No" line with the cleaning validation activity declared in Section VI.

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AXIS 4 — DEVICE-SPECIFIC COMPLIANCE (2026 CONTEXT)

Finding 6 — "Basic" Documentation Level declared without architectural justification [Red]

Axis : Device-Specific Compliance Page reference: 510(k) Summary, Performance Testing section (page 7)

Cited text :

"The software for the Device is determined as a **'Basic' documentation leve**l per FDA Guidance Document 'Content of Premarket Submissions for Device Software Functions'"

Risk analysis. The device architecture described in Section IV combines a wearable sensor, a device-based Medical Device Data System (MDDS) gateway, a cloud-based MDDS, a cloud-based configuration system, and a cloud-based healthcare professional interface. It supports notification of healthcare professionals when physiological data fall outside clinician-specified parameters, which influences clinical decision-making. The data are intended as an aid to diagnosis, disease management, and treatment.

Under the June 2023 final guidance, "Basic" documentation level applies when failure or latent flaws in the software would not present a probable risk of serious injury or death. For a Class II patient monitoring device with cloud-mediated clinician notifications, the Basic designation is defensible only if the risk analysis documents explicitly why the software's failure modes do not reach the Enhanced threshold. The Summary contains no such justification. Under current review climate, a reviewer is likely to request the risk-based rationale for the Basic designation.

Recommended fix. Add a paragraph explicitly mapping the device's intended use to the Basic documentation level, with cross-reference to the risk management file. If the analysis cannot defend the Basic designation, plan for Enhanced documentation in subsequent submissions.

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Finding 7 — Cybersecurity declarations limited to a single sentence [Red]

Axis 4: Device-Specific Compliance Page reference: 510(k) Summary, Performance Testing section (page 8)

Cited text :

"**Cybersecurity** risk assessment and controls of the Device was carried out per the FDA guidance document 'Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions'"

Risk analysis. The entire Cybersecurity declaration is a single sentence pointing to the FDA guidance. The Summary contains no mention of a threat model, no architectural cybersecurity description, no Software Bill of Materials (SBOM), and no end-to-end security characterization between sensor, gateway, and cloud components. For a device transmitting patient physiological data via Bluetooth and cloud infrastructure, this level of disclosure was already thin under the September 2023 guidance applicable at submission time.

Under the current 2026 review climate, this single-sentence Cybersecurity section would not survive RTA review. The SBOM has been a mandatory submission requirement since June 2025. The 2023 cybersecurity guidance expects an explicit threat model, security control mapping, and vulnerability management plan. The absence of all three elements is the most likely RTA blocker in this submission profile if re-filed today.

Recommended fix. Develop a dedicated Cybersecurity section with: SBOM in machine-readable format, threat model summary, security controls aligned to AAMI TIR57 or UL 2900-2-1, and vulnerability management plan.

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Finding 8 — Biocompatibility standard versions and reprocessing parameters not specified [Yellow]

Axis : Device-Specific Compliance Page reference: 510(k) Summary, Performance Testing section (page 7)

Cited text :

"All skin-contacting materials meet or exceed the biocompatibility requirements per testing against ISO 10993-5 and ISO 10993-10 standards." "Cleaning validation — testing validates cleaning and disinfection instructions for multiple-patient use."

Risk analysis. Two clarity gaps are bundled here.

First, consensus standards are revised periodically and their test thresholds change. Citing ISO 10993-5 and ISO 10993-10 without specifying the publication year or the FDA recognition number introduces unnecessary ambiguity. The reviewer must verify that the tests match the versions currently recognized by the FDA.

Second, for a reusable medical device, cleaning validation must specify the validated disinfectant family, the number of reprocessing cycles tested, and the material compatibility thresholds. The Summary mentions that a protocol was validated but omits all parameters. The reviewer cannot independently assess whether the validated reprocessing approach is consistent with typical institutional disinfection workflows.

Recommended fix. Add publication years to all ISO 10993 references (for example, ISO 10993-5:2009 and ISO 10993-10:2010, both currently recognized by the FDA). Specify the disinfection class validated (low-level versus intermediate-level), name the chemical families or specific wipes approved, and state the number of reprocessing cycles tested.

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Conclusion

The audited submission (K241101, BioButton System) was cleared by the FDA on September 26, 2024.

The documentary analysis identified 8 clarity gaps across the 4 axes:

4 Red findings.

- Performance comparison anchored to an undeclared device (**BioSticker K191614**).
- Major Single-use to Multiple-use design transition justified in one word, with an internal contradiction on reprocessing.
- "Basic" software Documentation Level declared without architectural risk justification.
- Cybersecurity declarations limited to a single sentence, with no SBOM, threat model, or control mapping.

4 Yellow findings.

- Truncated device name in document headers.
- "Patient" versus "User" drift across IFU, Summary text, and comparison table.
- ISO 14971 absent from the Safety standards matrix.
- Biocompatibility standard versions and multi-patient reprocessing parameters unspecified.

These gaps did not block clearance under 2024 review conditions. Under the current 2026 review climate, the strict application of RTA criteria, the mandatory SBOM requirement since June 2025, and reviewer workforce reduction at CDRH transform several of these gaps into systematic AI request triggers. The typical delay generated is 45 to 60 days per AI letter.

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For connected wearable devices, the absence of formal ISO 14971 declarations, the underdeveloped cybersecurity sections, and the unjustified Documentation Level designation are now among the most frequent causes of AI requests under current FDA review. These risks can be neutralized upstream of submission with a clarity audit before filing.

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