Device Information

Device Name: A&D MEDICAL UA-651 DIGITAL BLOOD PRESSURE MONITOR

K Number: K141160

Product Code: DXN (System, Measurement, Blood-Pressure, Non-Invasive)

Regulation: 21 CFR 870.1130

Device Class: Class II

Assessment Date: 12/11/2025

Assessment Outcome

Likely Manageable via Letter-to-File

Description of Change

Before Change:

App trend graph sometimes truncates at 23:50, even though underlying 24-hour data is intact. IFU mentions a historical '24-hour display limitation'.

After Change:

Bug fixed so graph shows full 24 hours. IFU text updated to remove mention of the old display limitation. No new clinical claims or features.

Reason for Change:

Fix UI defect and align labeling with actual behavior; no change to intended use.

Risk Assessment Summary

Risk Level Change: LOW

Change Type Impact Summary

Labeling Impact:

Clarifying or narrowing changes -> may be documented in change control record.

Software Impact:

Minor software updates within original clearance -> manageable via letter-to-file.

Decision Tree Analysis

Step 1 - Software / Function Change

Question: Does this software change modify or add any user-facing or clinical function related to the device's intended use, or otherwise affect intended use?

Answer: NO

Rationale: This change does not meet the criteria for this assessment step.

Step 2 - Software / Risk Assessment

Question: Does your risk analysis identify any new or increased risks related to this software change?

Answer: NO

Rationale: This change does not meet the criteria for this assessment step.

Step 3 - Software / Architecture Change

Question: Does this change modify the software architecture or introduce a major structural or technological change?

Answer: NO

Rationale: This change does not meet the criteria for this assessment step.

Step 4 - Software / Performance Change

Question: Does this software change alter performance specifications or algorithm behavior (e.g., accuracy, thresholds, timing)?

Answer: NO

Rationale: This change does not meet the criteria for this assessment step.

Step 5 - Labeling / Intended Use

Question: Does the change alter the device's intended use (including new disease, condition, anatomical site, or patient population)?

Answer: NO

Rationale: This change does not meet the criteria for this assessment step.

Step 6 - Labeling / Clarification

Question: Is the change limited to narrowing the indication or clarifying wording, without broadening use or changing the fundamental intended use?

Answer: YES

Rationale: The change primarily clarifies wording or removes outdated text without changing the fundamental intended use or safety profile.

Conclusion

Based on the decision tree analysis, the regulatory pathway for this change is: Likely Manageable via Letter-to-File. A letter-to-file with supporting documentation is likely sufficient. The change primarily adds or strengthens warnings without introducing new uses or fundamental changes to the device.

Recommendations & Next Actions

1. Prepare a Letter-to-File with supporting documentation demonstrating the change does not require a new 510(k).
2. Provide verification/validation documentation showing the device still meets originally cleared acceptance criteria.
3. File this assessment report and supporting documentation in the DHF/QMS under change control.
4. Maintain all supporting documentation (test reports, risk analyses, labeling drafts) in the DHF/QMS.

Disclaimer:

This assessment is informational and does not guarantee FDA decisions. Final regulatory responsibility remains with the manufacturer. Consult with a qualified regulatory affairs professional for definitive guidance.