NORTHSTAR BIOMEDICAL

CARDIAC DIAGNOSTICS ▪ DIGITAL HEALTH

510(k) PREMARKET NOTIFICATION

AcuTrace™ ECG PATCH

Ambulatory electrocardiographic monitoring system

Submission type	Traditional 510(k) — illustrative dossier
Regulation	21 CFR 870.2800; Product Code DSI
Applicant	Northstar Biomedical, Inc., Boston, Massachusetts, USA
Document ID	NB-510K-024 Rev 1.0
Submission date	August 2, 2026

IMPORTANT NOTICE

This is a fully populated, fictional training example designed to demonstrate the structure and visual language of a medical-device submission. It is **not** an actual FDA submission, clearance, authorization, or clinical recommendation. Device names, entities, identifiers, test reports, and results are illustrative.

Document control

Field	Value	Field	Value
Document number	NB-510K-024	Revision	1.0
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Classification	Confidential	Review cycle	Annual or upon change
Submission pathway	Traditional 510(k)	Submission format	eSTAR-aligned dossier

Approval record

Role	Name / responsibility	Disposition	Date
Regulatory Affairs	Maya Chen, RAC — submission owner	Approved	Aug 2, 2026
Quality Assurance	Daniel Okafor — design-control compliance	Approved	Aug 2, 2026
Clinical Affairs	Dr. Lena Ortiz — clinical evidence	Approved	Aug 1, 2026
Engineering	Arjun Mehta — technical file owner	Approved	Aug 1, 2026

Revision history

Rev.	Date	Change description	Author
0.1	Jun 12, 2026	Initial submission framework and evidence map.	M. Chen
0.8	Jul 18, 2026	Added verification, usability, and cybersecurity summaries.	M. Chen
1.0	Aug 2, 2026	Approved issue; all review comments resolved.	M. Chen

Submission conventions

Report identifiers shown in monospace map to controlled records in the illustrative design history file. Unless otherwise stated, all acceptance criteria were predefined in approved protocols, all testing used production-equivalent devices, and deviations were assessed under the quality system before report approval.

Contents

1 Executive summary

Device	AcuTrace™ ECG Patch, Model ATP-100, hardware revision C
Applicant	Northstar Biomedical, Inc., 45 Meridian Way, Boston, MA 02110, USA
Common name	Ambulatory electrocardiographic monitor
Classification	Class II; 21 CFR 870.2800; Product Code DSI
Predicate	iRhythm Zio® XT System (K190593), used here as an illustrative comparator
Use environment	Home, ambulatory, and professional healthcare environments
Patient contact	Intact skin; surface contact; up to 14 days

The AcuTrace™ ECG Patch is a prescription, single-patient-use, non-sterile wearable system that continuously records a single-channel electrocardiogram (ECG) for up to 14 days. Following the wear period, encrypted ECG data are transferred to the AcuTrace Analysis Portal, where automated algorithms identify candidate rhythm events for review by qualified healthcare professionals. The system does not provide real-time alarms, emergency notification, or autonomous diagnosis.

The subject device has the same intended use and comparable technological characteristics to the predicate. Differences in adhesive geometry, data-transfer method, memory capacity, and analysis software do not raise new questions of safety or effectiveness. Risk controls were verified through electrical safety, electromagnetic compatibility (EMC), environmental, mechanical, wireless, software, cybersecurity, biocompatibility, human-factors, and clinical-performance testing.

Regulatory conclusion

The compiled evidence supports the conclusion that the subject device is as safe and effective as the identified predicate for the proposed intended use. All predefined system-level acceptance criteria were met, and all residual risks were evaluated as acceptable when weighed against the anticipated clinical benefits.

1.1 Submission contents at a glance

Sec.	Module	Primary evidence	Status
2	Administrative information	Applicant, pathway, device classification	CLOSED
3–5	Device and equivalence	Description, indications, predicate comparison	CLOSED
6	Risk management	ISO 14971 risk file and benefit–risk conclusion	CLOSED
7–11	Performance	Bench, software, cybersecurity, biological, clinical	PASS
12–14	Labeling and declarations	Labeling, standards, traceability	CLOSED

2 Administrative information

2.1 Applicant and correspondent

Item	Information
Applicant	Northstar Biomedical, Inc., 45 Meridian Way, Boston, Massachusetts 02110, USA
Official correspondent	Maya Chen, RAC, Director of Regulatory Affairs
Contact	+1 617 555 0142; regulatory@northstar-biomedical.example
Manufacturing site	Northstar Biomedical Operations, 9100 Horizon Drive, Minneapolis, Minnesota 55401, USA
Quality system	21 CFR Part 820 / ISO 13485:2016-aligned quality management system
Establishment identifier	Fictional training identifier: NSB-3011847

2.2 Regulatory pathway rationale

The device is an external ambulatory ECG recorder under 21 CFR 870.2800. A Traditional 510(k) pathway is appropriate because the system has a legally marketed predicate with the same intended use and because the technological differences can be addressed through established performance methods. The software includes algorithmic event detection, but every candidate event requires professional review before inclusion in the final report.

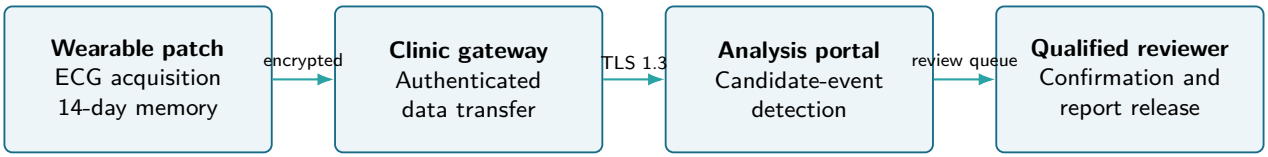
2.3 Truthful and accuracy statement

For this illustrative dossier, the authorized signatories certify that the information represented is complete and accurate within the fictional design record, that no material fact has knowingly been omitted, and that cited reports correspond to the summarized results. This statement demonstrates placement and content only; it carries no legal effect.

3 Device description

3.1 System overview

The system consists of the wearable patch, a reusable clinic gateway, the cloud-hosted analysis portal, and a clinician-facing report. The patch acquires and stores the ECG. At the end of the monitoring period, the gateway uploads an encrypted record. The portal performs signal-quality assessment and flags candidate rhythm events. A qualified reviewer confirms or rejects the candidates and releases a report to the ordering clinician.



3.2 Principal components

Component	Identifier	Function	Key specification
ECG patch	ATP-100	Acquires, digitizes, and stores one ECG channel	250 Hz; 16-bit; 0.05–40 Hz
Electrode / adhesive	ATP-E14	Conductive interface and skin fixation	Hydrogel; 220 cm^2; 14-day contact
Clinic gateway	ATG-200	Secure data upload and integrity verification	USB-C; Wi-Fi 802.11n; SHA-256 check
Analysis portal	ATS 3.2	Signal segmentation and candidate-event detection	Web application; role-based access
Clinician report	ATR-3	Presents reviewed findings and signal-quality metrics	PDF/A; audit-linked release

3.3 Operating principles

Two Ag/AgCl electrodes detect surface biopotentials. A low-noise analog front end filters and amplifies the differential signal before analog-to-digital conversion. Firmware timestamps and stores the signal in encrypted flash memory. The device has one patient control: pressing the symptom button places an event marker in the record. A status light provides brief feedback for activation, event marking, and fault conditions.

3.4 Technical specifications

Parameter	Specification	Parameter	Specification
Dimensions / mass	124 × 50 × 12 mm; 34 g	Recording duration	Up to 14 consecutive days
Ingress protection	IPX7	Applied part	Type BF
Power source	Sealed 3.0 V lithium cell	Wireless radio	Bluetooth Low Energy, upload only
Operating range	5–40 °C; 15–90% RH	Storage range	−20–55 °C
Expected shelf life	18 months	Sterility	Supplied non-sterile
Data capacity	360 hours ECG plus metadata	Clock accuracy	±30 ppm

3.5 Configurations and accessories

The ATP-100 patch is supplied in adult and pediatric-fit adhesive configurations. Electronics, firmware, signal path, and analysis are identical. The pediatric-fit configuration changes only the perimeter geometry and is intended for patients weighing at least 10 kg. The ATG-200 gateway, application tool, placement guide, return pouch, and clinician quick-reference card are included accessories.

4 Indications for use

Proposed indications for use

The AcuTrace™ ECG Patch is intended to continuously record and store single-channel ambulatory electrocardiographic data for up to 14 days in adult and pediatric patients weighing 10 kg or more who may have symptoms suggestive of cardiac arrhythmia. Recorded data are analyzed to identify candidate episodes of atrial fibrillation, tachycardia, bradycardia, pauses, and patient-marked events for review by qualified healthcare professionals. The device is available by prescription only and is not intended to provide real-time monitoring, alarms, or emergency response.

4.1 Intended users and environments

- **Patient / caregiver:** applies the patch after instruction, records symptoms, and returns the device after wear.
- **Healthcare professional:** orders monitoring, reviews the released report, and makes clinical decisions.
- **Qualified ECG reviewer:** verifies algorithm-selected events and authorizes the report.
- **Use environments:** home and ambulatory settings during wear; professional healthcare and controlled office environments during setup, transfer, review, and reporting.

4.2 Contraindications and limitations

The device is not intended for patients with known adhesive allergy, compromised skin at the application site, or a condition requiring real-time cardiac surveillance. It is not an implantable device, a life-supporting device, a defibrillator, or a substitute for emergency medical evaluation. MRI exposure, external defibrillation over the device, and use in explosive atmospheres are prohibited.

5 Substantial equivalence

5.1 Predicate-device comparison

Characteristic	Subject: AcuTrace ECG Patch	Predicate: Zio XT System
Intended use	Long-term ambulatory ECG recording with retrospective analysis and professional review	Long-term ambulatory ECG recording with retrospective analysis and professional review
Prescription status	Prescription use	Prescription use
Patient population	Adults and pediatric patients ≥10 kg	Adults and pediatric patients, per cleared labeling
Recording period	Up to 14 days	Up to 14 days
ECG configuration	Single-channel, two-electrode	Single-channel, two-electrode
Sampling / resolution	250 Hz / 16 bit	Proprietary; adequate for intended purpose
Patient interface	Chest-worn adhesive patch; event button	Chest-worn adhesive patch; event button
Analysis	Automated candidate detection followed by qualified review	Automated analysis followed by qualified review
Reporting	Retrospective clinician report; no real-time alarm	Retrospective clinician report; no real-time alarm
Data transfer	Encrypted electronic upload through clinic gateway	Physical return and controlled data extraction
Biocompatibility	Surface device; intact skin; prolonged contact	Surface device; intact skin; prolonged contact
Power	Sealed primary lithium cell	Sealed primary battery

5.2 Assessment of differences

The subject device introduces electronic upload, a different adhesive perimeter, increased solid-state memory, and a redesigned event-detection pipeline. These changes do not alter the intended use or fundamental scientific technology. Upload security and integrity were evaluated through cybersecurity, transport, and end-to-end record-reconciliation testing. Adhesive changes were addressed through biocompatibility, peel, wear, and usability testing. Algorithm changes were evaluated against an independent, adjudicated clinical dataset.

Substantial-equivalence determination

The similarities in intended use, operating principle, patient interface, monitoring duration, professional review, and output support equivalence. The identified differences are bounded by recognized methods and do not raise different questions of safety or effectiveness.

6 Risk management

Risk management was performed throughout the product lifecycle in accordance with ISO 14971:2019. The plan defines severity and probability scales, acceptability criteria, risk-control verification, production feedback, and post-production review. The risk-management report is `RMF-ATP-100-006`.

6.1 Risk evaluation model

Initial risk is estimated from severity (S1 negligible to S5 catastrophic) and probability (P1 remote to P5 frequent). Risk controls follow the hierarchy of inherently safe design, protective measures, and information for safety. Residual risk is accepted only when controls are verified and benefit–risk remains favorable.

Severity \ Probability	P1	P2	P3	P4	P5
S5	L	M	H	H	H
S4	L	M	M	H	H
S3	L	L	M	M	H
S2	L	L	L	M	M
S1	L	L	L	L	M

6.2 Representative hazard analysis

Hazard / harm	Principal controls	Initial	Verification evidence	Residual
Missed or false rhythm event; delayed care	Signal-quality logic; validated algorithm; mandatory professional review; labeling	High	ALG-VAL-014; CLN-021	MEDIUM
Skin irritation or sensitization	Material selection; ISO 10993 evaluation; site-preparation and removal instructions	Medium	BIO-017; HF-012	LOW
Electrical or thermal injury	Current limiting; sealed enclosure; battery protection; temperature monitoring	High	ES-60601-011	LOW
Data associated with wrong patient	Two-identifier workflow; barcode binding; record-integrity checks; audit trail	High	SYS-VAL-033	LOW
Unauthorized disclosure or modification	Encryption; least privilege; signed updates; monitoring; vulnerability process	High	CYB-THR-009; PEN-008	MEDIUM
Use error during placement	Shaped liner; anatomical diagram; placement check; training and usability validation	Medium	HF-012	LOW

No unacceptable residual risks remain. Medium residual risks are subject to complaint trending, cybersecurity monitoring, and periodic safety review. The overall residual-risk profile is acceptable in view of the benefit of extended rhythm capture and professional interpretation.

7 Non-clinical performance testing

All testing used final or production-equivalent configurations. Protocols specified sample rationale, conditioning, acceptance criteria, and statistical treatment before execution.

Test domain	Method / report	Result summary	Outcome
Electrical safety	IEC 60601-1; `ES-60601-011`	Leakage, dielectric strength, temperature, mechanical, and fault testing met limits.	**PASS**
EMC	IEC 60601-1-2; `EMC-004`	Emissions and immunity met home-healthcare limits with no loss of essential performance.	**PASS**
Ambulatory ECG	IEC 60601-2-47; `ECG-047-009`	Gain, bandwidth, noise, common-mode rejection, and rhythm response met criteria.	**PASS**
Ingress protection	IEC 60529 IPX7; `ENV-018`	No harmful water ingress after 1 m immersion for 30 minutes.	**PASS**
Mechanical durability	`MECH-026`	Drop, flex, torsion, button-cycle, and package-distribution tests passed.	**PASS**
Environmental	`ENV-021`	Functional after temperature/humidity cycling and labeled storage extremes.	**PASS**
Battery / transport	IEC 60086-4; UN 38.3; `BAT-010`	Capacity margin supported 14-day use; transport sequence passed.	**PASS**
Wireless coexistence	ANSI C63.27; `RF-016`	Upload recovered safely under representative interference; ECG acquisition unaffected.	**PASS**
Data integrity	`SYS-VAL-033`	120/120 end-to-end records reconciled bit-for-bit after upload.	**PASS**
Adhesive performance	`ADH-013`	Wear retention met target; removal force remained within specified range.	**PASS**
Packaging / shelf life	ASTM D4169; accelerated aging; `PKG-019`	Package integrity and functionality supported an 18-month shelf life.	**PASS**

7.1 Essential performance

Essential performance is accurate acquisition, preservation, and time alignment of ECG data such that no hazardous corruption is presented as valid data. Fault handling suppresses invalid segments, records diagnostic events, and prevents report release when integrity checks fail. EMC and single-fault testing demonstrated maintenance of essential performance or transition to a detectable safe state.

8 Software documentation

Software documentation follows IEC 62304:2006+A1:2015 lifecycle processes. The overall software safety classification is **Class B**: a software failure could contribute to non-serious injury through inaccurate or delayed information, while professional review and clinical context remain independent controls.

8.1 Architecture and configuration

Software item	Version	Primary function	Deployment
Patch firmware	2.4.1	Acquisition, storage, event marking, diagnostics	Locked embedded image
Gateway software	1.8.0	Device authentication, upload, integrity checks	Managed clinic appliance
Analysis services	3.2.0	Signal quality and candidate-event detection	Segmented cloud service
Review portal	3.2.0	Human review, audit trail, report release	Validated web application
Report generator	3.2.0	Controlled rendering and archival output	Server-side service

8.2 Verification and validation summary

Activity	Coverage / result	Report
Unit verification	2,846 automated tests; 100% requirements coverage; 91% branch coverage	SW-UT-041
Integration testing	428 interface and fault-injection cases; all expected results observed	SW-INT-029
System validation	312 workflows across supported browsers, roles, and boundary conditions	SYS-VAL-033
Algorithm validation	Independent adjudicated records; patient-level split; locked model and thresholds	ALG-VAL-014
Anomaly assessment	7 deferred anomalies; none affects safety, essential performance, or intended use	SW-ANOM-017
SOUP assessment	Inventory, license, vulnerability, and functional-risk assessments completed	SOUP-022

Software requirements are bidirectionally traceable to architecture, risk controls, tests, and results. Release records identify the compiler, build environment, third-party components, configuration items, signing keys, and reproducible build hash.

9 Cybersecurity

The security case is based on threat modeling, secure design, verification, transparency, and postmarket vulnerability management. Security risk is evaluated separately and linked to safety risk where compromise could affect data integrity, availability, or patient association.

9.1 Security controls

Objective	Design controls	Verification
Authenticity	Device certificates; mutual authentication; signed firmware and services	Certificate misuse, downgrade, and signature-negative tests
Authorization	Role-based access; least privilege; session timeout; dual control for release	Role matrix and privilege-escalation testing
Confidentiality	AES-256 at rest; TLS 1.3 in transit; managed key rotation	Protocol inspection and cryptographic configuration review
Integrity	SHA-256 record manifests; sequence and patient-binding checks; immutable audit trail	Bit-level reconciliation and tamper-detection testing
Availability	Queued upload; backup and restore; service monitoring; rate limiting	Recovery exercises and load / denial-of-service resilience tests
Updatability	Authenticated updates; rollback protection; software bill of materials (SBOM)	Update interruption, invalid image, and rollback testing

9.2 Security evidence and postmarket process

Threat modeling used STRIDE and abuse-case analysis across trust boundaries. Independent penetration testing found no critical or high-severity exploitable findings at closure. The machine-readable SBOM is maintained in CycloneDX format. The coordinated vulnerability-disclosure process defines intake, triage, exploitability assessment, remediation targets, customer communication, and regulatory reporting. Security updates are supported for the labeled service life plus two years.

Cybersecurity residual-risk conclusion

Known vulnerabilities were assessed against exploitability, clinical impact, and compensating controls. No uncontrolled vulnerability was identified that could create unacceptable safety risk. Moderate residual security risks are monitored through dependency scanning, threat intelligence, logging, and periodic penetration testing.

10 Biocompatibility

The patient-contacting adhesive and electrode assembly is categorized as a surface device contacting intact skin for prolonged duration (>24 hours to 30 days). The biological evaluation follows ISO 10993-1:2018 and includes material characterization, supplier controls, toxicological assessment, and endpoint testing on the final finished device.

Endpoint	Method	Result	Outcome
Cytotoxicity	ISO 10993-5	Grade 0 reactivity; cell viability met acceptance criterion	**PASS**
Sensitization	ISO 10993-10 / 10993-23	No evidence of skin sensitization	**PASS**
Irritation	ISO 10993-23	Negligible irritation response	**PASS**
Chemical characterization	ISO 10993-18	Extractables characterized under exaggerated conditions	**PASS**
Toxicological risk	ISO 10993-17	Margins of safety acceptable for identified constituents	**PASS**

No new colorants, natural rubber latex, phthalates, or animal-derived materials are used in the patient-contacting assembly. Manufacturing residues are controlled through validated processes and change control. The biological evaluation report `BIO-017` concludes that the device is biocompatible for its intended type and duration of contact.

11 Clinical performance

Clinical algorithm performance was evaluated retrospectively using an independent, multi-center dataset that was not used for algorithm development or threshold selection. Reference annotations were established by two board-certified cardiologists, with disagreement resolved by a third adjudicator. Analysis was performed at both episode and patient levels with prespecified confidence intervals.

11.1 Dataset characteristics

Characteristic	Value	Characteristic	Value
Unique patients	612	Total analyzable ECG	82,440 hours
Age range	12–91 years	Female participants	51.8%
Recording sites	7 U.S. centers	Median wear duration	10.8 days
Adjudicated target episodes	3,184	Prespecified exclusions	2.7% of signal

11.2 Primary performance results

Rhythm class	Sensitivity	PPV	95% CI, sensitivity	Acceptance criterion
Atrial fibrillation	97.2%	96.5%	96.1–98.1%	Lower CI bound ≥90%
Tachycardia	96.1%	94.8%	94.7–97.2%	Lower CI bound ≥90%
Bradycardia	95.4%	95.9%	93.8–96.7%	Lower CI bound ≥90%
Pause	94.6%	92.7%	91.9–96.3%	Lower CI bound ≥90%

All primary endpoints met their prespecified acceptance criteria. Subgroup analyses by age, sex, skin tone, site, and signal-quality quartile did not identify a clinically meaningful performance disparity. Pediatric observations were consistent with overall performance, with no new safety signal; labeling limits use to patients weighing at least 10 kg based on fit and wear-validation evidence.

11.3 Adverse events and clinical conclusion

No serious device-related adverse event occurred in the clinical-use cohort of 184 participants. Twelve participants (6.5%) experienced mild, transient erythema; two (1.1%) discontinued wear because of skin discomfort. No report was associated with a device-related delay in urgent intervention. The clinical evidence supports performance for the proposed use when outputs are reviewed by qualified professionals.

12 Human factors and usability

The usability-engineering process follows IEC 62366-1:2015+A1:2020. Critical tasks were identified from use-related risk analysis, formative studies, complaint analogues, and expert review. The summative validation included 45 representative users: 24 adult patients/caregivers, 9 pediatric caregivers, 6 technicians, and 6 ECG reviewers.

Critical task	Potential consequence	Validation outcome
Confirm patient identity	Record assigned to wrong patient	45/45 completed correctly without assistance
Prepare skin and place patch	Poor signal, early detachment, skin injury	44/45 initially correct; one recovered using on-label instruction
Recognize contraindication	Inappropriate application	45/45 identified relevant warning
Mark a symptom	Event not linked to symptoms	45/45 completed correctly
Respond to status indication	Loss of recording or incomplete data	45/45 selected correct action
Return / upload record	Delay or loss of data	45/45 completed; all integrity checks passed
Review and release report	Incorrect clinical information released	12/12 professional users completed correctly

Observed use difficulties did not result in a new hazardous situation, and no critical task produced an unmitigated use error. Residual use-related risks are acceptable. Validated labeling includes plain-language steps, high-contrast diagrams, tactile alignment cues, and distinct status-light patterns.

13 Labeling summary

13.1 Package label

AcuTrace™ ECG Patch

Model ATP-100 • Ambulatory ECG monitoring system

Catalog	ATP-100	Lot	NS260720A
Use by	2028-01-31	UDI-DI	00850000124107
Storage	−20 to 55 °C	Quantity	1 patch

Rx only. Single patient use. Non-sterile. Refer to the instructions for use before application.

Keep dry until opened. Contains a lithium metal cell; do not crush, incinerate, or expose to MRI.

13.2 Core warnings and precautions

- **No real-time alarm:** the system does not provide immediate notification of arrhythmia. Seek emergency assistance for symptoms of a medical emergency.
- **Skin safety:** do not place on broken, irritated, or infected skin. Remove the patch and contact a healthcare professional for severe discomfort or a spreading skin reaction.
- **Interference and procedures:** remove before MRI. Do not apply defibrillation pads over the patch. Follow clinical direction for other procedures.
- **Data completeness:** detachment, improper placement, electromagnetic disturbance, or depleted battery can reduce analyzable recording time.

13.3 Patient workflow

1. Confirm the labeled patient and expiration date; prepare intact skin at the prescribed location.
2. Apply the patch using the numbered liner tabs and press the perimeter firmly for 30 seconds.
3. Press the center button once to begin recording; verify the green activation indication.
4. During symptoms, press the button once and record the symptom and time in the diary or application.
5. At the end of wear, peel the patch back slowly, place it in the return pouch, and follow the clinic's return instructions.

14 Standards and guidance

Standard / guidance	Edition used	Application	Conformity
ISO 13485	2016	Quality management system	Full
ISO 14971	2019	Medical-device risk management	Full
IEC 60601-1	Ed. 3.2	Basic safety and essential performance	Full
IEC 60601-1-2	Ed. 4.1	Electromagnetic disturbances	Full
IEC 60601-2-47	2012	Ambulatory ECG systems	Applicable clauses
IEC 62304	2006+A1:2015	Software lifecycle processes	Full
IEC 62366-1	2015+A1:2020	Usability engineering	Full
ISO 10993-1	2018	Biological evaluation planning	Full
ISO 10993-5 / -10 / -23	Current editions	Cytotoxicity, sensitization, irritation	Full
IEC 60529	Ed. 2.2	IPX7 enclosure testing	Applicable clauses
ANSI C63.27	2021	Wireless coexistence	Full
NIST SP 800-218	2022	Secure software development framework	Applied

Standards were applied to the editions identified in approved test protocols. Any partial application is documented through a clause-level rationale. Current FDA-recognized consensus-standard status and applicable guidance should be confirmed immediately before a real submission.

15 Traceability and evidence index

Claim / control	Requirement	Verification / validation evidence	Risk linkage
14-day recording	SYS-101	Battery margin, memory capacity, long-duration recording: `BAT-010`, `ECG-047-009`	H-03, H-07
ECG fidelity	SYS-118	Gain, noise, bandwidth, CMRR, waveform response: `ECG-047-009`	H-01, H-02
Record integrity	SYS-131	End-to-end reconciliation, fault injection: `SYS-VAL-033`	H-04, H-09
Candidate-event performance	ALG-204	Locked algorithm clinical validation: `ALG-VAL-014`, `CLN-021`	H-01, H-02
Professional review	UI-312	Role and workflow validation: `HF-012`, `SYS-VAL-033`	H-01, H-10
Skin-contact safety	MAT-411	Biological evaluation and adhesive wear: `BIO-017`, `ADH-013`	H-05
Electrical safety	HW-501	IEC 60601-1 and battery tests: `ES-60601-011`, `BAT-010`	H-06, H-08
Security / privacy	SEC-601	Threat model, penetration test, SBOM, cryptographic tests: `CYB-THR-009`, `PEN-008`	H-04, H-09
Correct placement	UI-701	Summative usability validation: `HF-012`	H-03, H-05
Shelf life	PKG-801	Accelerated aging and distribution simulation: `PKG-019`	H-03, H-06

15.1 Submission evidence register

The controlled submission archive includes full protocols and reports, raw-data locations, statistical-analysis plans, standards declarations, software documentation, design reviews, labeling, and signed approvals. Every document is checksum-verified at publishing. The evidence index is reviewed against the eSTAR response set before final transmission.

16 Overall conclusion

The AcuTrace™ ECG Patch has the same intended use and comparable technological characteristics as the identified predicate. Differences are supported by targeted testing and do not raise new questions of safety or effectiveness. Verification and validation demonstrate that the system meets its design requirements and maintains essential performance under intended and reasonably foreseeable conditions of use.

The risk-management process identified hazards associated with signal quality, algorithm output, patient association, skin contact, electrical safety, use error, and cybersecurity. Risk controls were implemented and verified. Clinical-performance and human-factors evidence support the proposed patient population, intended users, and use environments. On the basis of the evidence summarized in this dossier, the subject device is considered substantially equivalent to the predicate for its proposed intended use.

Final dossier status

Design verification	**PASS**	All planned activities complete
Design validation	**PASS**	Intended-use needs demonstrated
Residual-risk review	**CLOSED**	Overall residual risk acceptable
Submission readiness	**CLOSED**	Illustrative dossier approved for issue

Prepared by

Maya Chen, RAC
Director, Regulatory Affairs
August 2, 2026

Approved by

Daniel Okafor
Vice President, Quality Assurance
August 2, 2026

END OF CONTROLLED DOCUMENT

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