Assignment 3

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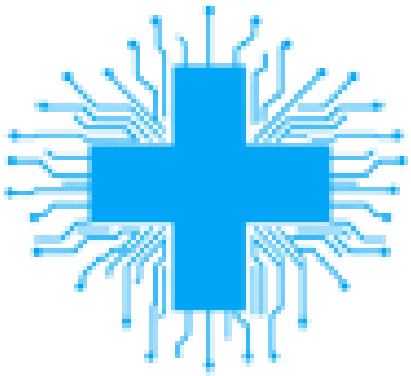
RGA6370 – Advanced Regulatory Writing: Medical Device Submissions

Submitted to: Professor Angel Estrada

February 12, 2026.

PRE-SUBMISSION (Q-SUB) PACKAGE



RadHealth, Inc.

StrokeMate: AI-Enabled CT Imaging System for Acute Neurovascular Event Detection

COVER LETTER

Date: 02/12/2026

Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Control Center

RE: Pre-Submission (Pre-Sub) Request
For StrokeMate: AI-Enabled CT Imaging System for Acute Neurovascular Event Detection

1. Contact Information

Submitter:
RadHealth, Inc.

Primary Contact:
Name: Aastha Dave
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2. Q-Sub Type
☑ Pre-Submission (Pre-Sub)

3. Method of Feedback Requested
☑ Written Feedback Followed by Virtual Meeting

4. Meeting Information

Proposed Meeting Format: Virtual (videoconference)
Requested Duration: 60 minutes

Proposed Dates (ET):

February 25, 2026
March 03, 2026

March 05, 2026
Proposed Company Attendees:
Director, Regulatory Affairs
Lead AI Scientist
Clinical Affairs Lead
Software Engineering Lead
RadHealth requests inclusion of appropriate FDA Digital Health and Cybersecurity subject matter experts.

5. Planned Follow-On Submission

RadHealth intends to submit a 510(k) Premarket Notification following FDA feedback.

6. Purpose of This Pre-Submission

The purpose of this Pre-Submission is to obtain FDA feedback on four focused substantial topics prior to finalizing clinical validation and software documentation for a planned 510(k) submission:

I. Clinical performance endpoints and validation strategy
II. Use of retrospective datasets for AI validation
III. Cybersecurity and data integrity controls
IV. Software documentation level and SaMD considerations

RadHealth believes early FDA alignment will ensure efficient and least burdensome development consistent with FDA expectations.

DEVICE DESCRIPTION

2.1 Device Name

RadHealth StrokeMate: AI-Enabled CT Imaging System

2.2 Device Overview

The RadHealth system integrates standard non-contrast cranial CT imaging with a proprietary artificial intelligence (AI) algorithm designed to assist clinicians in detecting, characterizing, and scoring acute neurovascular events, including:

Ischemic stroke

Intracerebral hemorrhage

Transient ischemic attack (TIA)

The AI algorithm processes CT image data and provides:

Quantitative probability scores

Visual region-of-interest overlays

Structured output reports for clinical review

The device does not provide autonomous diagnosis and functions solely as clinical decision support.

2.3 Technological Characteristics

AI-based image analysis software

Integration with hospital PACS systems

Secure cloud or on-premises processing architecture

Locked algorithm (no adaptive learning post-deployment)

2.4 Proposed Indications for Use

The RadHealth CT imaging system is indicated for use in adult patients suspected of acute ischemic stroke, hemorrhagic stroke, or transient ischemic attack (TIA). The device provides quantitative and qualitative image analysis outputs to assist trained healthcare professionals in clinical assessment. The device does not provide autonomous diagnosis.

REGULATORY HISTORY

RadHealth has had no prior Q-Submissions or marketing submissions for this device.

RadHealth anticipates submitting a Class II 510(k) Premarket Notification and believes the device will be reviewed as Software as a Medical Device (SaMD) integrated into CT imaging workflows.

BACKGROUND INFORMATION

4.1 Clinical Rationale

Rapid stroke identification is critical for time-sensitive interventions such as thrombolysis and thrombectomy. Variability in interpretation and workflow delays contribute to treatment delays.

4.2 Development Status

- ✓ Retrospective multi-center dataset training completed
- ✓ Preliminary performance metrics generated
- ✓ Design controls implemented under 21 CFR 820.30
- ✓ Cybersecurity risk assessment initiated

SPECIFIC QUESTIONS FOR FDA FEEDBACK

RadHealth seeks FDA feedback on four substantial topics that are specific to the device's integration of AI-based image analysis within acute stroke workflows.

5.1 Predicate Strategy and Substantial Equivalence Framing

Background

RadHealth intends to pursue a 510(k) pathway. The device:

- Performs non-contrast cranial CT acquisition
- Applies a locked AI algorithm for detection of ischemic stroke and intracranial hemorrhage
- Provides probability scores and visual overlays
- Flags suspected critical findings within the PACS environment
- Unlike traditional CAD systems, the device also generates structured stroke severity scoring outputs (e.g., ASPECTS estimation) intended to assist triage prioritization but not to provide autonomous diagnosis.

Question 5.1.1

RadHealth anticipates referencing a predicate device cleared for AI-assisted detection of intracranial hemorrhage or large vessel occlusion on CT. However, the RadHealth system includes an integrated structured severity scoring output (e.g., automated ASPECTS estimation), which may not be present in the predicate.

Does FDA agree that inclusion of structured severity scoring outputs may be addressed within the substantial equivalence framework as an additional technological characteristic, provided performance validation demonstrates comparable safety and effectiveness and labeling clearly states the adjunctive nature of the output?

Question 5.1.2

If FDA believes that structured severity scoring introduces a new intended use or different questions of safety and effectiveness relative to potential predicates, would FDA recommend narrowing the initial Indications for Use to detection-only claims and deferring severity scoring to a subsequent submission?

5.2 Ground Truth Determination and Adjudication Model

Background

RadHealth proposes retrospective validation using multi-center CT datasets. Ground truth will be established via:

- Independent blinded review by three board-certified neuroradiologists
- Majority consensus adjudication
- Access to follow-up imaging and clinical outcomes only during adjudication, not initial reads
- The device is intended to assist in early triage decisions prior to MRI confirmation.

Question 5.2.1

Given that acute ischemic changes on early non-contrast CT may be subtle and not always visible at presentation, does FDA agree that a ground truth model incorporating follow-up imaging (e.g., MRI within 24–48 hours) for adjudication is appropriate, even though such confirmatory imaging would not be available to the device in real-time use?

Question 5.2.2

RadHealth proposes to stratify performance analysis by time-from-symptom-onset (≤6 hours vs >6 hours) due to known differences in CT detectability of ischemic changes.

Does FDA agree that stratified performance reporting by clinically relevant time windows is appropriate to ensure labeling transparency and avoid overstating device sensitivity in early presentations?

5.3 AI Performance Drift and Locked Algorithm Control

Background

The RadHealth AI algorithm is locked at time of submission and will not adapt post-deployment. However:

- Imaging protocols vary across institutions
- Scanner manufacturers differ
- Patient populations differ geographically

RadHealth proposes:

- Pre-specified performance monitoring metrics
- Real-world performance surveillance
- Threshold-based internal triggers for future software modification
- No automatic model updating without new FDA submission

Question 5.3.1

Given the known variability in CT acquisition parameters across institutions, does FDA agree that pre-clearance validation across multiple scanner manufacturers and acquisition protocols is sufficient to mitigate foreseeable generalizability risks without inclusion of a Predetermined Change Control Plan (PCCP) at this time?

Question 5.3.2

If FDA believes that algorithm performance variability across institutions constitutes a foreseeable modification pathway, would FDA recommend inclusion of a PCCP under section 515C to define future model refinement boundaries, or would traditional 510(k) modifications be more appropriate for this device type?

5.4 Cybersecurity Risk Modeling for AI-Assisted Triage Systems

Background

The device:

- Interfaces with PACS via DICOM
- Transmits data within hospital networks
- Generates AI-derived probability scores that may influence triage prioritization
- RadHealth has identified the following unique AI-specific threat vectors:
- Adversarial manipulation of image input
- Data poisoning via corrupted DICOM files
- Unauthorized modification of probability score outputs

RadHealth proposes:

- Input validation safeguards
- Image integrity verification checks
- Encryption of model weights
- Audit trail logging of all AI outputs

Question 5.4.1

Does FDA agree that adversarial input manipulation represents a credible threat vector for this device type, and that simulation-based robustness testing against adversarial perturbations should be included in cybersecurity documentation for a 510(k)?

Question 5.4.2

RadHealth proposes to classify probability score alteration or corruption as a high-severity cybersecurity hazard due to potential triage delay implications.

Does FDA agree with this risk categorization approach under a cybersecurity risk management framework aligned with ISO 14971 and current FDA cybersecurity guidance?

DRAFT MEETING AGENDA

Q Sub request procedure:

- Introduction and device overview – 10 minutes
- Clinical validation endpoints – 15 minutes
- Retrospective validation strategy – 15 minutes
- Cybersecurity and software documentation – 15 minutes
- Summary and action items – 5 minutes

APPENDICES

Appendix A – System Architecture Diagram

Appendix B – Preliminary AI Performance Summary

Appendix C – Cybersecurity Risk Summary

Appendix D – Draft Indications for Use

REFERENCES:

[1] U.S. Food and Drug Administration. (2025, May 29). *Requests for feedback and meetings for medical device submissions: The Q-Submission program: Guidance for industry and Food and Drug Administration staff*. Center for Devices and Radiological Health & Center for Biologics Evaluation and Research. https://www.fda.gov

[2] U.S. Food and Drug Administration. (2025, May 29). *Electronic submission template for medical device Q-submissions: Draft guidance for industry and Food and Drug Administration staff*. Center for Devices and Radiological Health & Center for Biologics Evaluation and Research. https://www.fda.gov