ASSIGNMENT

Proposed Design Control and Development Plan

For AI-Enabled CT Imaging System for Acute Neurovascular Event Detection

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EXECUTIVE SUMMARY

Design Control Phase	Activity	Purpose	Key Deliverables / Records	Responsible Role
Design Planning	Establish design control framework	Define how design activities will be conducted and controlled	• Design & Development Plan • Project timeline & milestones • Roles & responsibilities matrix	Quality Assurance Manager (Owner) Project Manager Regulatory Affairs Manager
User Needs	Identify clinical and workflow needs	Ensure device addresses real-world user expectations	• User Needs Document • Clinical workflow analysis • Stakeholder input summaries	Clinical Affairs Lead (Owner) Human Factors Engineer Product Manager
Design Inputs	Translate user needs into measurable requirements	Define regulatory, technical, safety, and performance requirements	• Design Input Requirements Document • Regulatory requirements list • Applicable standards list	Systems Engineer (Owner) Regulatory Affairs Specialist Quality Assurance
Design Outputs	Develop design solutions	Produce specifications that meet design inputs	• System architecture diagrams • Software & AI specifications • Labeling drafts (IFU, warnings) • Manufacturing specifications	R&D Engineering Lead (Owner) Software Architect Technical Writer
Design Review (Planned)	Cross-functional review of design stage	Confirm readiness to proceed and identify gaps	• Design Review agendas & minutes • Action item logs • Review approvals	Quality Assurance (Facilitator) R&D Lead Regulatory Affairs Clinical Affairs
Design Verification	Confirm outputs meet inputs	Demonstrate the product was built correctly	• Verification protocols • Software unit & integration test reports • Algorithm performance testing reports • Traceability Matrix	Verification/Test Engineer (Owner) Software QA Engineer Quality Assurance
Design Review (Post-Verification)	Review verification results	Ensure all input requirements are met	• Verification review minutes • Approved verification summary	Quality Assurance (Owner) R&D Lead Regulatory Affairs
Design Validation	Confirm device meets user needs and intended use	Demonstrate the right product was built	• Validation plan & protocols • Simulated use testing reports • Usability / human factors study report • Clinical performance evaluation summary	Clinical Affairs Lead (Owner) Human Factors Engineer Quality Assurance
Design Review (Post-Validation)	Final design confirmation	Approve readiness for transfer and submission	• Validation review minutes • Final design approval records	Executive Sponsor Quality Assurance Regulatory Affairs
Design Transfer	Transfer design to production	Ensure manufacturing can consistently produce the device	• Design Transfer Plan • Approved drawings & specifications • Manufacturing SOPs • Training records	Manufacturing Engineer (Owner) Quality Assurance Operations Manager
Risk Management (Ongoing)	Identify, evaluate, and control risks	Ensure risks are reduced to acceptable levels	• Risk Management Plan • Hazard Analysis / FMEA • Risk control verification records • Residual risk assessment	Risk Management Lead / QA (Owner) R&D Engineering Clinical Affairs
Design History File (DHF)	Maintain design evidence	Demonstrate compliance with design controls	• Complete DHF including all design, verification, validation, review, and risk records	Quality Assurance (Owner) Document Control

Proposed Design Control and Development Plan

RadHealth, Inc.
Product: AI-Enabled CT Imaging System for Acute Neurovascular Event Detection

I. Introduction

1. Product Description and Rationale

RadHealth is developing a computed tomography (CT) imaging system integrated with an advanced artificial intelligence (AI) algorithm designed to assist clinicians in the detection, characterization, and scoring of acute neurovascular events, including ischemic stroke, intracerebral hemorrhage, and transient ischemic attack (TIA). This product was selected due to the significant unmet clinical need for rapid and accurate triage of patients presenting with suspected stroke, where time-to-diagnosis is critical to patient outcomes. Integrating AI-driven image analysis with standard CT imaging has the potential to enhance diagnostic confidence, reduce interpretation time, and support clinical decision-making in emergency and acute care settings.

2. Intended Use

The RadHealth CT imaging system is intended to acquire, process, and analyze cranial CT images and provide AI-assisted outputs to support healthcare professionals in identifying and characterizing suspected neurovascular abnormalities.

3. 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 clinicians in clinical assessment. The device does not provide autonomous diagnosis and is intended for use as an adjunct to standard clinical evaluation and imaging interpretation.

4. Intended Market

The intended initial market for the device is the United States. The device is intended for use in emergency departments, comprehensive stroke centers, and acute care hospitals. Intended users include radiologists, neurologists, emergency physicians, and multidisciplinary stroke care teams. The product is anticipated to be regulated as a Class II medical device and will follow the FDA Premarket Notification (510(k)) regulatory pathway.

II. Concept and Feasibility

The device concept originated from identified gaps in acute stroke imaging workflows, including variability in image interpretation and delays in diagnosis during time-critical clinical scenarios. Early concept and feasibility activities included clinical needs assessments with radiologists and neurologists, preliminary AI algorithm feasibility studies using retrospective CT datasets, development of a high-level system architecture, and initial design reviews to confirm technical feasibility, regulatory classification, and intended use alignment.

These activities supported progression into formal design and development under FDA Design Controls. Key roles involved during this phase included Clinical Advisors, AI Research Scientists, Systems Engineers, and Regulatory Affairs Management.

III. User Needs and Stakeholder Needs

User needs include rapid identification of stroke-related findings, clear and interpretable AI outputs that integrate into existing clinical workflows, high sensitivity for critical findings such as hemorrhage or large vessel occlusion, and minimal impact on imaging or interpretation time. Stakeholder and regulatory needs include compliance with FDA Quality System Regulation (21 CFR 820.30), alignment with FDA guidance for AI/ML-enabled medical devices, implementation of cybersecurity and data integrity controls, and interoperability with hospital picture archiving and communication systems (PACS). These activities are supported by Human Factors Engineering, Regulatory Affairs, and Clinical Affairs functions.

IV. Design Planning

The goal of the design and development effort is to develop a safe, effective, and regulatory-compliant Class II CT imaging device with AI-based decision support. The scope of development includes hardware integration, AI algorithm development, software validation, labeling development, and preparation of regulatory submissions. Key deliverables include the Design and Development Plan, documentation of user needs and design inputs, software and algorithm specifications, verification and validation protocols and reports, a Risk Management File, and a Design History File (DHF). The estimated timeline includes approximately three months for concept and planning, nine to twelve months for design and development, and six months for verification and validation. Project execution is supported by a cross-functional team including a Project Manager, R&D Engineering, Quality Assurance, and Regulatory Affairs.

V. Design Inputs

Design inputs are derived from user needs, regulatory requirements, and applicable standards. Inputs include compliance with FDA 21 CFR Part 820 design controls, applicable 510(k) requirements for CT imaging systems and Software as a Medical Device (SaMD), defined performance requirements such as sensitivity and specificity thresholds for clot and bleed detection, safety requirements including electrical safety and radiation dose considerations, software requirements addressing AI algorithm performance, explainability, and update controls, and labeling requirements including instructions for use, warnings, limitations, and guidance on interpretation of AI outputs. Design inputs are developed and maintained by Systems Engineering, Software Architecture, and Regulatory Affairs.

VI. Design Outputs

Design outputs translate design input requirements into controlled specifications and documentation. Outputs include system architecture diagrams and technical specifications, software and AI algorithm documentation, AI performance metrics and model training documentation, draft labeling and instructions for use, and manufacturing and test

specifications. These outputs are generated and maintained by R&D Engineering, Software Development, and Technical Writing functions.

VII. Design Verification
Design verification activities confirm that design outputs meet defined design input requirements. Verification includes software unit and integration testing, AI algorithm performance testing using annotated datasets, compliance testing against applicable technical and safety standards, and verification of traceability between design inputs, outputs, and test results. Verification activities are conducted by Verification Engineering, Software Test Engineering, and Quality Assurance.

VIII. Design Validation
Design validation activities confirm that the device meets user needs and intended use under actual or simulated use conditions. Validation includes simulated use testing with clinicians, usability and human factors studies, clinical performance evaluation using representative datasets, and labeling comprehension studies. Validation activities are led by Clinical Affairs, Human Factors Engineering, and Quality Assurance.

IX. Design Reviews
Formal design reviews are conducted at defined milestones, including completion of design planning, completion of design inputs, completion of design verification, and completion of design validation. Design reviews are attended by cross-functional representatives from Quality Assurance, Regulatory Affairs, Research and Development, Clinical Affairs, and Executive Leadership.

X. Design Transfer
Design transfer activities ensure that the final, approved design is accurately transferred to manufacturing and production. Activities include transfer of approved specifications, drawings, and software builds, development of manufacturing and quality system SOPs, and training of production personnel. Design transfer is supported by Manufacturing Engineering, Quality Assurance, and Operations Management.

XI. Risk Management File
A Risk Management File is established and maintained in accordance with ISO 14971. Risk management activities begin early in the design phase and continue throughout development and validation. Documentation includes a Risk Management Plan, hazard analysis, risk evaluation and control measures, and residual risk assessment.

XII. Design History File (DHF)
A Design History File is maintained throughout the project lifecycle to demonstrate compliance with FDA design control requirements. The DHF includes the Design and Development Plan, design inputs and outputs, verification and validation records, design review documentation, and risk management records.