Design & Development Plan (DDP) EPIC ClearView Device

ORIGINATOR:

Name	Job Title	Signature	Date
Scott Pletzer	Quality & Program Management Director		08AUG12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder, Chief Executive Officer		8/8/12
Michael Stowell	Chief Financial Officer		8/8/12
Tom Blondi	President		8/8/12
Patsy Folio	Clinical Programs Director	Patsy Folio	8/8/12
Andrea Miller	Quality Assurance Manager		8/8/12
Daniel Miller	Manufacturing Engineer		8/8/12
Andrew Mason	Chief Technology Officer		8/8/12
Don Pegg	Senior Electrical Engineer	See attached SP 10Sep12	

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	08Aug12	Initial Release	S. Pletzer

EPIC RESEARCH DIAGNOSTICS	Design & Development Plan (DDP) EPIC ClearView Device

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1.0 PURPOSE

1.1 The purpose is to define the Design & Development Plan (DDP) for assembling, testing, and releasing EPIC ClearView systems for commercial or investigational device exemption (IDE) use by EPIC Research & Diagnostics, Inc (EPIC).

1.2 This DDP is supported by the content of DD-026, EPIC ClearView Device Design Control Statement which documents the design control history for the ClearView Device development. DD-026 summarizes the design controls utilized during early development through the present of the ClearView Device, and this DDP summarizes design controls going forward through device commercialization.

1.3 This DDP is also supported by DDP-003, Clinical Build Project Plan which documents the design controls required for clinical builds to date and sets precedence for requirements of this DDP.

1.4 This DDP satisfies in part the requirements to address and close EPIC's CAPA #1007.

2.0 SCOPE

2.1 The DDP outlines the design control activities required to systematically assess the design of the EPIC ClearView Device. As such, the DDP provides guidance regarding all activities necessary to assemble, test, and release EPIC ClearView systems consisting of the ClearView Device loaded with EPIC ClearView Firmware (part 06690 Rev. A), a computer system (1282-1511 rev. 001) loaded with the EPIC ClearView Software (ClearView) and all relevant accessories.

2.2 The EPIC ClearView systems released under this DDP can be commercially sold and distributed, or used in IDE investigations.

2.3 This DDP does not cover the development of software. Any reference to software is as a tool only for the assessment of the device. Software development activities are documented in separate design history files. .

3.0 REFERENCE DOCUMENTS

3.1 DD-005, Risk Management Plan for EPIC ClearView System

3.2 DD-012, EPIC ClearView Product Requirements – User

3.3 DD-013, EPIC ClearView Product Requirements Matrix- Software

3.4 DD-014, EPIC Product Requirements - Device

3.5 DD-015 000 EPIC ClearView Product Requirements - Accessories

3.6 DD-026, EPIC ClearView Device Design Control Statement

3.7 DDP-003, Clinical Build Project Plan

3.8 EG-001, Design Control Procedure

3.9 EG-012, Risk Management

3.10 Regulatory Documentation:

- FDA 21 CFR 820, Quality System Regulations (QSRs)
- ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- FDA's Design Control Guidance For Medical Device Manufacturers, March 11, 1997

4.0 PROJECT REQUIREMENTS

4.1 Design and development planning is initially documented via this DDP. Specific planning is maintained in a separate project plan by the Project Implementation Manager. This project plan is reviewed monthly by the project development team.

4.2 The necessary work instructions, inspection/test procedures, and forms will be approved and released in MJS Designs' quality system prior to continuing device builds under this DDP. Draft documentation will be allowed for any non-critical work instructions with proper written documentation and approval and/or controlled documents will be referenced.

4.3 A complete Device Master Record (DMR) will be created to document the approved procedures used in the assembly of the devices. A summary of the known assembly deviations will be generated and included in the review and approval of the DMR.

4.4 Design verification and validation testing will be performed by EPIC under a pre-approved test protocols to support established product requirements. All requirements of those protocols will need to be met or accepted with appropriate justification and supporting rational prior to release of ClearView Systems for commercial or clinical use.

4.5 Upon completion of the ClearView System Device Master Record (DMR), the final ClearView System DMR will be compared to the Clinical Trial DMR generated as a part of DDP-003. The comparison will be made to ensure that the devices assembled are significantly equivalent to the predicate Clinical Trial DMR requirements. Any deviations/discrepancies will be identified and resolved prior to the completion of any commercial distribution of devices built under this DDP.

4.6 Product requirements for devices have been established under:

- DD-012, EPIC ClearView Product Requirements – User
- DD-014, EPIC Product Requirements - Device
- DD-015 000 EPIC ClearView Product Requirements - Accessories

The above product requirements documents serve as the roadmap for verification and validation activities, and will be revised as required throughout the commercialization process. Product

requirements will be reviewed and incorporated into verification and validation testing to demonstrate they have been met.

4.7 Risk analysis activities (including component level and process analysis) will be performed in accordance with Risk Management Plan for EPIC ClearView System, DD-005.

4.8 A review of all component and material specifications will be conducted to ensure that all design outputs are properly documented among EPIC, PADT, and MJS.

4.9 Release requirements for devices will be established by MJS and EPIC in accordance with their respective Quality Management System requirements.

4.10 Design transfer activities will be done, either on the entire device or subassemblies, as needed to meet the commercial product build schedule, and documented via design reviews.

5.0 RESPONSIBILITIES

5.1 Information Technology (IT) – development and release of ClearView software and firmware.

5.2 Quality & Operations – oversight of design control activities for device, assembly, testing, and release.

5.3 Quality, Manufacturing Engineering, & Clinical - performing design verification and validation testing (including protocol & report generation)

5.4 MJS Designs, Inc. (MJS) – generating necessary work instructions, inspection/test procedures, and forms used in the assembly, testing, and release of devices to EPIC.

5.5 PADT, Inc. (PADT) – provide assistance as necessary to MJS in the development of work instructions, inspection/test procedures, and forms and performing firmware functional validation and device performance verification testing (including protocol & report generation). Participates in design control activities as assigned.

6.0 ORGANIZATION, INTERFACES, RESPONSIBILITES, AND APPROVAL AUTHORITY

6.1 EPIC will have overall responsibility for all device design control and build activities.

6.2 Work instructions, inspection/test procedures, and forms for the assembly of the ClearView Device that are approved by EPIC, PADT, and MJS will be controlled and released within the MJS quality system. Work instructions, inspection/test procedures and forms for the assembly and kitting of all other ClearView System components (e.g., computer system, UPS, cleaning supplies, etc.) will be controlled and released within EPIC's quality system.

6.3 Design verification/validation test protocols and reports will be authored and approved by EPIC.

6.4 The final release of these devices will be the responsibility of EPIC .

6.5 EPIC's Program Manager will be responsible for day-to-day management and oversight of this DDP and communicating relevant project information to team members.

6.6 Approval Authority will be executed according to the following matrix:

Name	Title	Company	Review Approval Required
Nancy Rizzo	Founder and CEO, CSO	EPIC	Design Review and Approvals
Tom Blondi	President	EPIC	Design Review and Approvals
Michael Stowell	CFO and V.P. of Operations	EPIC	Design Review and Approvals
Andy Mason	Chief Technology Officer	EPIC	Design Review and Approvals
Patsy Folio	Clinical Programs Director	EPIC	Design Review and Approvals
Scott Pletzer	Quality and Program Management Director	EPIC	• Design Review and Approvals • Alternate for EPIC QA Manager approval
Andrea Miller	Quality Assurance Manager	EPIC	• Design Review and Approvals • Assembly documentation approvals (includes work instructions, inspection/test procedures, and forms) • Verification and Validation Protocols and Reports
Dan Miller	Manufacturing Engineer	EPIC	• Design Review and Approvals • Assembly documentation approvals (includes work instructions, inspection/test procedures, and forms) • Verification and Validation Protocols and Reports
Jan Ayres	Project Implementation Manager	EPIC	Maintain a detailed project plan
Don Pegg	Senior Electrical Engineer	PADT	• Design Review and Approvals • Assembly documentation approvals (includes work instructions, inspection/test procedures, and forms) • Verification and Validation Protocols and Reports

7.0 MAJOR TASKS (MILESTONES) & SCHEDULE

7.1 Engineer ClearView device

7.2 Build commercial lot of 32

7.3 Develop packaging

7.4 Develop labeling

7.5 Design Verification and Validation Testing

7.6 Finalize Risk Analysis

7.7 IEC 60601 certification

7.8 FDA approval

7.9 CE Mark

7.10 Final design review and approval

7.11 Design release for use

The above milestones and dates will be closely tracked and documented as part of EPIC's regularly scheduled staff and process review meetings. Changes to the schedule and milestones can occur within those forums without the need to revise this DDP, unless significant project requirement changes occur. Additionally, other DDPs may be generated if required to support this DDP.

8.0 DESIGN VERIFICATION & VALIDATION APPROACH

8.1 Design verification and validation will be performed by testing device functionality to the established requirements and specifications via an input/output product requirements matrix.

8.2 The final results of the verification and validation testing will be formalized through design verification and validation protocols to be written prior to performance of the testing and summarized into final reports which outline the results of all verification and validation testing.

8.3 Design verification and validation activities can occur concurrently, and the general outline of the steps are:

8.3.1. Development & approval of design verification and validation test protocols.

8.3.2. Execution of design verification and validation test protocols.

8.3.3. Summary of design verification and validation testing into summary reports.

8.3.4. Approval of design verification and validation test reports.

8.3.5. Review of testing to determine that all design requirements have been adequately tested and the results demonstrate device performance meets the design requirements.

8.3.6. Clinical activities (e.g., trials) that support design validation will be managed via EPIC's Clinical group.

9.0 RISK ANALYSIS

9.1 A Risk Management Plan for EPIC ClearView System, DD-005, was initially approved on 4/3/12. This plan outlines the risk management approach and activities. All current and future risk management activities will be managed through this plan and in accordance with EG-012, Risk Management.

10.0 PROJECT CONSTRAINTS

10.1 Known project constraints at this time are identified and maintained in the detailed project plan. Any additional constraints will be managed through EPIC staff and process review meetings and/or documented via revisions of this plan.

11.0 DESIGN HISTORY FILE (DHF)

11.1 The outputs of this effort will be generated and added to the Design History File (DHF) in accordance with the requirements of EG-001, Design Control.