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	Design Control	

REVISION LOG

Rev [##]	Eff. Date [yyymmdd]	CO [CO-####-##]	Brief Description of Change	Author [initials]
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1.0 **Purpose**

The purpose of this document is to outline the procedures to follow to develop new, or modify existing products. Compliance with the requirements of this procedure and those of the referenced documents helps to assure that:

- Development of new products and modifications to existing products are controlled processes;
- Checks and balances applied to product development activities are defined;
- Design function and interface responsibilities are assigned, design input and output are defined, and design output meets design input requirements as demonstrated by design verification and validation activities;
- The product design is exposed to persons with viewpoints and opinions other than those of the Project Team;
- Oversights that may adversely affect the quality, safety, and efficacy of the design are minimized;
- Anticipated risks associated with use of the design are acceptable.

2.0 **Scope / Application**

This document applies to the development of all Class II and Class III products (as defined by the US Food and Drug Administration (FDA)), Class I devices automated with computer software, and several devices identified in 21 CFR 820.30 (1996). Compliance with this procedure and the referenced procedures also assures that the requirements of ISO 13485 are met for the design of all items that meet the definition of a medical device in the Medical Devices Directive, MDD 93/42 EC as amended.

3.0 **Responsibility**

3.1. **Executive Management**

Executive Management is responsible for

- 3.1.1. Selecting a Project Team team with the required training or experience and ensuring that experience/ training is documented in the individuals' training records.
- 3.1.2. Assuring that assignments for specific design-related activities are defined in the procedures that define those activities.

Executive Management is synonymous with Top Management, and either term may be used to describe Management with Executive Responsibility in any Quality System procedure.

4.0 **Definitions, References, and Applicable Documents, History**

4.1. **Definitions**

Design and Development Plan - A plan, in symbolic and/ or written form, that indicates the necessary tasks required to develop products that are safe and effective and meet

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customer requirements. The plan identifies the timing of tasks and their inter-relationships, and assigns responsibility for each task.

Design input - The physical and performance requirements of a device that are used as a basis for device design [21 CFR 820.3 (1996)]

Design output - The results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the Device Master Record. The total finished design output consists of the device, its packaging and labeling, and the Device Master Record. [21 CFR 820.3 (1996)]

Design review - A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet those requirements, and to identify problems

Design verification - Confirmation by examination and provision of objective evidence that specific design requirements have been fulfilled [21 CFR 820.3 (1996)]

Design validation - Establishing by objective evidence that device specifications conform with user needs and intended use(s) [21 CFR 820.3 (1996)]

Design transfer - A documented procedure that ensures that the device design is correctly translated into production and quality control specifications and procedures, and that all production and quality personnel are appropriately trained. Training procedures shall be documented. [21 CFR 820.3 (1996)]

Design change - Procedures for the identification, documentation, and written justification, review, and approval of design changes before their implementation

Design History File - A compilation of records which describes the design history of a finished device [21 CFR 820.3 (1996)] NOTE: The DHF is a subset of the Device Master Record

Employee Training - A documented procedure that ensures that personnel are given or possess adequate training, information, and other tools required to consistently meet the requirements of their assigned responsibilities

Device Master Record - The Device Master Record (DMR) is a compilation of records containing the procedures and specifications for a finished device [21 CFR 820.3 (1996)]

Risk (Hazard) Analysis - Documented, systematic application of procedures to identify, analyze, control, and monitor risks associated with the use and misuse of a device

United States Food and Drug Administration (FDA) – an agency within the U.S. Department of Health and Human Services that is responsible for protecting public health. The FDA is responsible for assuring that manufacturers comply with Design Control regulation requirements

4.2. References and Applicable Documents

4.2.1. External References

Section 520 (f) of the Safe Medical Devices Act of 1990

21 CFR 820.3 (1996): Definitions

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21 CFR 820.30 (1996): Design controls

ISO 13485:2003 - *Medical Devices – Quality management systems – Requirements for regulatory purposes, Design and Development*

Design Control Guidance for Medical Device Manufacturers (FDA guidance document, available online)

FDA Design Control Inspectional Strategy (FDA guidance document, available online)

Do It by Design: an Introduction to Human Factors in Medical Devices (FDA guidance document, available online)

4.2.2. Internal References

SOP-001 Document Creation and Control

SOP-002 Change Order Initiation, Approval and Notification

SOP-004 Risk Management

SOP-005 Design History File

SOP-006 Design and Development Planning

SOP-007 Design Input

SOP-009 Design Output

SOP-010 Design Verification

SOP-011 Design Validation

SOP-012 Design Review

SOP-013 Design Transfer

SOP-017 Training

SOP-015 Device Master Record

4.3. History

Not applicable

5.0 Safety Considerations

Not applicable

6.0 Procedures

Executive Management will ensure that the design and development requirements relating to a product are appropriate and address the intended use of the device, including the needs of the user and patient. Procedures shall be established and maintained to ensure compliance with Design Control regulation requirements and relevant sections of ISO 13485:2003 - *Medical Devices – Quality management systems – Requirements for regulatory purposes, Design and Development*.

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NOTE: All of the following sections are based upon the Design Control requirements specified in 21 CFR 820.30 (1996) and relevant sections of ISO13485:2003 - *Medical Devices – Quality management systems – Requirements for regulatory purposes, Design and Development*

6.1. Design and Development Planning (SOP-006)

Design and development of products shall be planned and controlled. During design and development planning, the organization shall determine the responsibilities and authorities for design and development; the design and development stages; and the review, verification, and validation that are appropriate to each design and development project. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

6.2. Design Input (SOP-007)

6.2.1. Design input shall include:

- Functional and performance requirements according to the intended use(s);
- Applicable statutory and regulatory requirements;
- Where applicable, information derived from previous similar designs;
- Other requirements essential for design and development;
- Output(s) of Risk Management.

6.2.2. Requirements shall be complete, unambiguous, and not in conflict with each other. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s).

6.3. Design Output (SOP-009)

6.3.1. Procedures shall be established and maintained to ensure that design output is defined and documented in terms that allow an adequate verification of conformance to design input requirements.

6.3.2. Design output shall

- Contain or make reference to acceptance criteria;
- Ensure that those characteristics of the product that are essential for its safe and proper use are identified;
- Provide appropriate information for purchasing, production, and provision of service;
- Be documented, reviewed, and approved before release.

NOTE: Records of design outputs can include specifications, manufacturing procedures, engineering drawings, and laboratory (engineering) notebooks.

6.4. Risk/ Hazard Analysis (Risk Management SOP-004)

Risks associated with the intended use of the device shall be documented. The use of the device by all anticipated users in all anticipated end use environments are to be

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considered. When possible, risks are to be minimized by modifying the design of the device, its use environment, or by providing appropriate information to end users. Risk analysis and assessment shall be performed as part of an overall risk management process.

6.5. Design Review (SOP-012)

- 6.5.1.** Design reviews shall be conducted to evaluate the ability of the results of design and development activities to meet requirements, and to identify any problems and propose necessary actions.
- 6.5.2.** Procedures shall be established and maintained to ensure that systematic, formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development in accordance with planned arrangements. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed.
- 6.5.3.** The results of each design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the Design History File (DHF).

6.6. Design Change (SOP-001 and SOP-002)

- 6.6.1.** Design changes shall be identified and records maintained.
- 6.6.2.** The changes shall be reviewed, verified, and validated, as appropriate, and approved before their implementation.
- 6.6.3.** The review of design changes shall include evaluation of the effect of the changes on constituent parts and products already delivered as well as on any already completed Design Control activities, especially verification and validation.

NOTE: Design changes that occur during the life cycle of a product shall meet the relevant requirements of design change procedures.

6.7. Design Verification (SOP-010)

- 6.7.1.** Procedures for verifying the device design shall be established and maintained. Design verification shall ensure that the design output meets the design input requirements.
- 6.7.2.** Design verification may include activities such as
 - Performing alternative calculations;
 - Comparing the new design with a similar proven design, if available;
 - Undertaking tests and demonstrations;
 - Reviewing the design stage documents before release.

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6.8. Design Validation (SOP-011)

6.8.1. Procedures for validating the device design shall be established and maintained. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate.

6.8.2. Design Validation may include one or a combination of the following:

- Compilation and critical review of relevant scientific and clinical literature
- Historical evidence that similar designs and/ or materials are clinically safe
- Clinical investigation or trial to ensure clinical safety and efficacy or clinical performance, as required by national or regional regulations

NOTE: National or regional laws/ regulations may require clinical investigations. In some cases, local clinical investigations are required.

6.9. Design Transfer (SOP-013)

Procedures shall be established and maintained to ensure that the device design is correctly translated into production specifications, and that personnel are trained to perform their duties in the manufacture of the new design.

6.10. Design History File (SOP-005)

Design History Files (DHF) shall be established and maintained for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and all requirements of this procedure.

6.11. Device Master Record (SOP-015)

The DMR shall be complete and approved before the device is made available to end-users in situations other than those where the device is being evaluated to determine its safety and efficacy.