Section 16 – Software

The DripAssist includes software.

Software Level of Concern

In the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", 5/11/05, FDA recommends submission of documentation relative to the software Level of Concern. Level of Concern refers to "an estimate of the severity of injury that a device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use".

The guidance document also provides a method for classifying level of concern. Table 1 below provides answers to questions regarding the guidance document's Table 1, used to determine whether the software is of a ***major*** level of concern. Table 2 shows answers to the questions regarding the guidance document's Table 2, used to determine whether the software is of a ***moderate*** level of concern.

Table 1- Major Level of Concern	Answer	Reason
1. Does the Software Device qualify as Blood Establishment Computer Software?	[redacted]	
2. Is the Software Device intended to be used in combination with a drug or biologic?	[redacted]	[redacted]
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	[redacted]	[redacted]
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	[redacted]	[redacted]
a. Does the Software Device control a life supporting or life sustaining function?	[redacted]	[redacted]
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	[redacted]	[redacted]
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	[redacted]	[redacted]

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	[redacted]	[redacted]
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	[redacted]	[redacted].

Table 2 - Moderate Level of Concern	Answer	Reason
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	[redacted]	[redacted]
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	[redacted]	[redacted].
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	[redacted]	[redacted]

Based on the answers to the above question, the **Level of Concern** is **Moderate**.

Software Documentation

Software Description

The software controls the following functions:

- Takes button press inputs and updates the LCD display accordingly to accommodate user inputs.
- Controls LCD display.
- Monitors sensors [redacted] and uses this information to calculate flow rate. This function involves [redacted].
- Performs power management on all devices.
- Signals alarm under specific conditions.

[redacted]

Additional information can be found in Section 11 - Device Description.

Device Hazard Analysis
See 710-00008 Risk Assessment and 710-00005 FMEA spreadsheet (Attachment B) for these documents.

Software Requirements Specification
See document 710-00006 DripAssist requirements and specifications (Attachment B) for the SRS.

Architecture Design Chart
See document 720-00002 Software Flowchart (Attachment B) for an Architecture Design Chart.

Software Design Specification
See document 710-00007 (Attachment B) for the Software Design Specification.

Traceability Analysis
See 710-00004 (Attachment B) for the Traceability Analysis

Software Environment Description
The DripAssist firmware is created using a microchip integrated development environment (IDE). The tool includes the ability to compile the firmware as well as various libraries to support the embedded controllers. Included in the library are components used for standard math and I/O libraries, and graphics for the LCD.

For developing firmware, a distributed revision control system is used. New iterations of firmware can be developed independent of production versions, tested, and verified before being implemented as production firmware. Validation must be completed on all new major version changes to firmware.

Verification and Validation Documentation
The approach for Design Verification was [redacted]y.

At each stage of integration activities, [redacted] of the device.

[redacted]

[redacted]

2. [redacted]

3. [redacted]

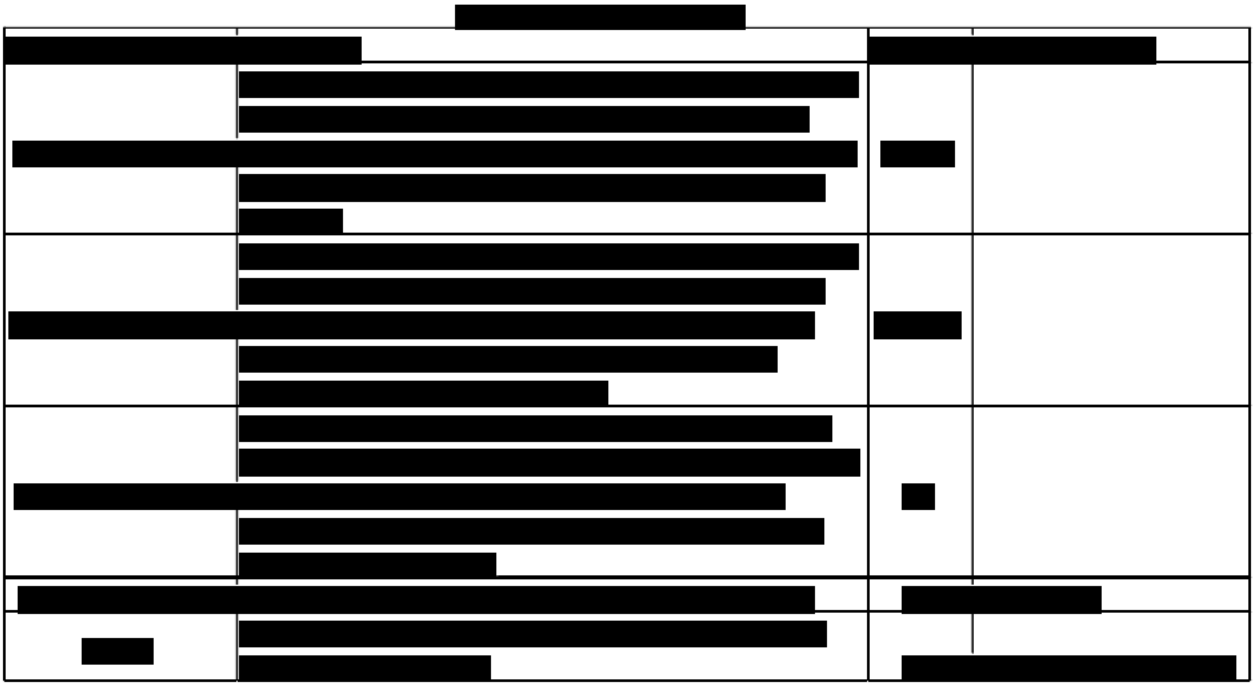
[redacted]

4. [redacted]

See 710-00003 (Attachment B) for the Design Verification and Validation report.

Revision Level History

[redacted]



[redacted]