**Purpose:** To document the Software Safety Classification and Essential Performance, based on the System Risk Analysis, for the following Medical Device Software:

|  |  |
| --- | --- |
| Product Name: | DYONICS Power II Control Unit |
| Catalog Number: | 72200873 |
| Software Number/Revision: | 73000196 Rev A |

**References:**

1. IEC 62304 Medical Device Software –Software Life Cycle Processes
2. ISO 14971 Medical Devices – Application of Risk Management to Medical Devices
3. 1400003 Software Development Process
4. 1400141 Risk Management Procedure
5. 16000043 Failure Modes Effects Analysis – DYONICS POWER II Control Unit
6. 15008083 System Software Architecture
7. 16500069 Essential Performance

After a review of the 16000043 DFMEA and the 15008083 Software Architecture Documents per Appendix A**,** the Software Items have been assigned the Software Safety Classifications with the highest correlating Severity Ranking in Table 1.

Table 1. Software Item Safety Classification

|  |  |  |
| --- | --- | --- |
| **Software Items** | **Item Implements Risk Mitigation** | **Safety Classification** |
| SYSTEM Controller Software | Yes | B |
| Motor Controller Software | Yes | B |
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| Safety Classification Rationale:  The following hazards where software failure could cause harm were considered:   * Inadvertent handpiece activation (Handpieces include MDUs and powered instruments, which are accessories to the DYONICS POWER II Control Unit), * Failure to maintain the blade speed within the pre-programmed range.   The team concluded that non-serious injury could occur, and therefore assigned software safety class of B. Non-serious injury from active therapeutic devices and surgically invasive devices intended for transient use is consistent with device classification specifications from the European medical directive, 93/42/ECC, and its related guidance, which considers such devices Class IIa. The primary potential safety hazards associated with the DYONICS POWER II are inadvertent handpiece activation, which could result in cutting is that is not intended, and failure to maintain blade speed within the pre-programmed range, which could result in breakage and/or shedding of the surgical disposable blades in the joint space. An assessment of complaints contained in Blades, Burrs, Shavers, and MDUs Clinical Evaluation Report, Document 16500214 Revision E and covering the period February 2009 through September 2019 was performed. All complaints related to inadvertent handpiece activation and blade speed/blade shedding were reviewed for severity and found to result in non-serious injury to the patient. This finding is consistent with the software safety Class B designation. |

**Software System Safety Classification:** Based on the classification of Software Items listed above, the overall Software System Safety Classification is determined to be B.

**Essential Performance is defined as:** Performance of Medical Electrical (ME) Equipment or Medical Electrical (ME) System clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk. See SOP 1400141 for definition of and actions required for unacceptable risk.

**Software’s Contribution to Essential Performance per DFMEA 16000043**:

| ID | Requirement Ref. | FMEA Item |
| --- | --- | --- |
| N/A | N/A | N/A |

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| Essential Performance Rationale:  Refer to 16500069 Essential Performance Rationale for the DYONICS POWER II. |

**APPROVALS:**

|  |  |  |  |
| --- | --- | --- | --- |
| **DEPARTMENT** | **NAME** | **TITLE** | **SIGNATURE/DATE** |
| **R&D** | **Douglas Tenney** | **Senior Staff Engineer** |  |
| **QA** | **Sai Ranjith Ramakrishnan Kumar** | **Senior Quality Engineer** |  |
| **RA** | **Mary Simchik** | **Regulatory Affairs Specialist II** |  |