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| Product Name: | DYONICS Power II Control Unit |
| Catalog Number: | 72200873 |
| Software Number/Revision: | 73000196 Rev A |
| Description of Product / Software and its intended use | System software for the DYONICS POWER II Controller / See IFU for intended use |

**Purpose:** Determine Level of Concern based on estimate of injury severity that a device could permit or inflict (directly or indirectly) on a patient or operator as a result of latent failures, design flaws, or use of software in a medical device or process.

**Table 1 Major Level of Concern**

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| **If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.** |
| 1. Does the Software Device qualify as Blood Establishment Computer Software? **NO**   (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.) |
| 1. Is the Software Device intended to be used in combination with a drug or biologic?   **NO** |
| 1. Is the Software Device an accessory to a medical device that has a Major Level of Concern?   **NO** |
| 1. 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: |
| * 1. Does the Software Device control a life supporting or life sustaining function?   **NO** |
| * 1. 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?   **NO** |
| * 1. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?   **NO** |
| * 1. 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? **NO** |
| * 1. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?   **NO** |

**Table 2 Moderate Level of Concern**

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| **If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.** |
| 1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?   **NO** |
| 1. 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?   **YES** |
| 1. 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?   **NO** |

**If the answers to all the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.**

**Level of Concern:**  Per Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – May 11, 2005; the Level of Concern is **MODERATE**.

**Rationale for Level of Concern:** Smith & Nephew internal operating procedure P/N 1400004 (EOP, Software Level of Concern Analysis) provides the basis for the rationale based on answers to the questions above while Risk Management Procedure P/N 1400141 provides definition of Serious and Minor Injury in relation to the product DFMEA. DFMEA 16000043 Rev P was reviewed and no items were identified that were more than moderate risk.

**APPROVALS:**

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| **DEPARTMENT** | **PRINT NAME** | **SIGNATURE** | **DATE** |
| **Research and Development** | **Douglas Tenney** |  |  |
| **Regulatory Affairs** | **Mary Simchik** |  |  |
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