

SPECIAL 510(k): Device Modification
Review Memorandum

To: THE FILE

RE: DOCUMENT NUMBER k111339

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. Medtronic Hemostasis Management System (HMS Plus), k101271; previously cleared device.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
This change was for the modification of the current HMS Plus hardware to replace several obsolete hardware components including the print circuit board assembly (PBCA), the ADU and printer controller. The HMS software was modified due to software unavailability requiring replacement of the operating system software, HMS Plus Boot Rom software, and software to run on the new microcontroller. Software modification also reflects removal of the porcine instrument setting to support easier device operation and eliminate operator confusion. The HMS Plus printer and mounts were modified due to obsolescence and its compatibility to the new computer PCBA. A reduction of the voltage settings was implemented to accommodate the new printer. Labeling was modified to update of the operator's manual and device labels to reference IEC 61010-1:2001, 2nd Edition standard, addition of the IVD symbols, and revision of the UL and MFR symbols.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and sample requirements. The differences are change in the HMS hardware, software, and removal of the porcine instrument setting. The mechanical differences are different mounts for the new printer and printer controller and the position of the printer controller PCBA from the base to the front enclosure of the device. (See section 6, page 1-22)
5. A **Design Control Activities Summary** which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. (See Section 7, pages 1-26 & 1-27)
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied. (See Appendix E, pages 1-284 through 1-311)
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, (See section 8, page 1-28) and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. (See section 8, page 1-29)
6. A **Truthful and Accurate Statement**, a **510(k) Summary** and the **Indications for Use Enclosure**. (Listed respectively under sections 11, 5 and page 1-7)

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the

design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.