K110193
pg 1 of 2

Attachment 6

510(k) Summary

FEB 2 4 2011

Submitter information:	St. Jude Medical Systems AB Palmbladsgatan 10 Box 6350, SE-751 35 Uppsala,SWEDEN Phone:(+46) 18161000
Contact:	Katrin Svensson
Date Prepared:	January 17, 2010
Proprietary Name:	FemoStop™ Femoral Compression System
Registration name:	Vascular Clamp
Product Code	DXC
Predicate Devices:	K024107 FemoStop® HD Femoral Compression System K062033 BP101 Digital Blood Pressure Monitor K080206 FemoStop™ Femoral Compression System

Description of the Device: This combination of FemoStop™ Femoral Compression is called FemoStop™ Gold and consists of an arch with a sterile pneumatic pressure dome, an integrated pump with a digital manometer and a belt. The pressure dome is placed over the vessel puncture site in the groin. The belt is placed around the patient. The dome applies mechanical pressure over the vessel puncture site to induce hemostasis. The pneumatic pressure in the dome is applied and regulated by a manual pump and displayed on a manometer. The arch and belt provide counter pressure for the dome.

Indication for Use of the Device: FemoStop™ Femoral Compression System is indicated for use in the compression for the femoral artery or vein after vessel cannulation, and in ultrasounded-guided compression repair of a femoral artery pseudoaneurysm.

Technical Characteristics: The technical characteristics of the actual FemoStop™ are identical to those of the predicate FemoStop™ Femoral Compression System. The main modification is that this version will be supplied without a hemostatic dressing and that the software in the manometer has been updated. The software modification consists of a 10 second activation delay and inclusion of additional error codes.

Substantial Equivalence and performance data: The modified device has the same fundamental technological characteristics as the predicate device. The software modification does not affect the intended use, operating principle, technology or manufacturing process. The following tests and quality assurance measures were applied to the development of the modified software:

- Software validation, including black-box testing.
- Application of risk management according to ISO 14971:2007 - Medical Devices- Application of risk management to medical devices.

The subject version of FemoStop™ Gold functioned as intended and conformed to the required specifications. No new issues of safety and effectiveness have been raised. Thus, the subject FemoStop™ Gold version is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

St. Jude Medical Systems AB
c/o Ms. Katrin Svensson
Regulatory Affairs Officer
Palmbladsgatan 10
Uppsala, Sweden SE-751 35

FEB 2 4 2011

Re: K110193
Trade/Device Name: FemoStop™ Gold
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: January 21, 2011
Received: January 24, 2011

Dear Ms. Svensson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

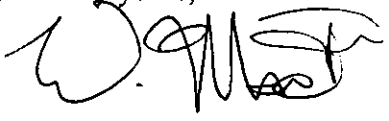
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known): K110193

Device Name: FemoStop™ Gold

Indications For Use: FemoStop Femoral Compression System is indicated for use in the compression of the femoral artery or vein after vessel cannulation and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110193