K093130

Section 4. 510(k) Summary

NOV - 4 2009

4.1 Applicant Information

Submitted by:	St. Jude Medical
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	Maple Grove, MN 55311

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Date Prepared:	1 October, 2009

4.2 Device Information

Classification Name:	Introducer, Catheter
Common Name:	Hemostasis Introducer
Trade Name:	Engage TR Introducer
Classification:	Class II per 21 CFR 870.1340
Product Code:	DYB

4.3 Device Description

The modified Engage TR Introducer is essentially a modification of the previously cleared Engage/Engage TR/Ultimum introducer (K091137). The modified Engage TR Introducer is intended to provide easy access to the vascular system, while providing convenient temporary closure of the access port during catheter exchanges. The Engage TR Introducer range in effective length is from 7cm to 25cm. The Engage TR Introducer sheaths included in the scope of this submission range in sizes from 4-6F ACT (Active Clotting Time). In addition, the

Engage TR Introducer has HPC coating on the sheath and it is compatible with 0.025" guidewires.

The Engage device consists of two primary components: the Hemostasis sheath assembly and the dilator. The Hemostasis sheath assembly is the vessel access device and the dilator fits inside the sheath providing support. The dilator lumen is designed to provide a close fit to appropriately sized guidewire. At the proximal end of the Hemostasis sheath is a snap-lock hub which is equipped with a Hemostasis valve and side port with approximately 8 cm of tubing attached and ending with a 3-way stopcock. Some of the Engage devices are packaged with FDA cleared devices such as guidewires and needles.

4.4 Intended Use

There is no change to the intended use of the modified Engage TR Inroducer as it is identical to the predicate Engage/Engage TR Introducer, K091137-*April 22, 2009.*
The introduction of angiographic catheters, closed end catheters, balloon catheters, and electrodes into a blood vessel (including but not limited to femoral, radial, and brachial access) where minimizing blood loss is essential.

4.5 Predicate Device Comparison/Technological Characteristics

The modified Engage TR Introducer included in this Special 510(k) submission shares the same intended use as the predicate Engage/Engage TR Introducer (K091137, April, 22, *2009*), which is indicated for the introduction of angiographic catheters, closed end catheters, balloon catheters, and electrodes into a blood vessel (including but not limited to femoral, radial, and brachial access) where minimizing blood loss is essential. The modified Engage TR Introducer, covered by this submission, is substantially equivalent to the St. Jude Medical Engage/Engage TR Introducer (K091137, April, 22, *2009*), Ultimum Hemostasis Introducer (*K001346, May 24, 2000*), Strada Carotid Guiding Sheath, (K070166, April 06, 2007), and Fast Cath Hemostasis Introducer (K914090, October 28, 1991).

The modifications to the Engage TR Introducer do not affect the intended use of the system and there is no alteration in the fundamental scientific technology of the device. The Engage TR Introducer covered by this Special 510(k) submission is similar in function and technological characteristics, mechanism of action and intended use as the market cleared predicated devices, Engage/Engage TR Introducer, Ultimum Hemostasis Introducer, Strada Carotid Guiding Sheath (K070166, April 06, 2007), and Fast-Cath Introducer (K091137, K001346, K070166 & K914090).

4.6 Test Summary

The Engage TR Introducer product family is required to pass predetermined design performance criteria. The summary of Engage TR test performance data is provided in this 510k submission. Based on passing verification specification criteria for functional, packaging, sterilization, biocompatibility, and shelf life tests, the Engage TR Introducer performs substantially equivalent to predicate devices. Given the scope of the modifications incorporated to create the proposed Engage TR Introducer, no additional animal or clinical data was deemed necessary.

4.7 Substantial Equivalence

The Engage TR Introducer covered by this submission is substantially equivalent to the previously cleared Engage/Engage TR Introducer (K091137, April, 22, 2009), Ultimum Hemostasis Introducer (K001346, May 24, 2000), Strada Carotid Guiding Sheath (K070166, April 06, 2007), and Fast Cath Hemostasis Introducer (K914090, October 28, 1991), given equivalent intended use, principles of operation and similar technological characteristics.

4.8 Conclusion

In conclusion, the modified Engage/Engage TR Introducer is substantially equivalent to the market cleared Engage/Engage TR Introducer, Ultimum Hemostasis Introducers, and Fast Cath Hemostasis Introducer (K091137, K001346, K070166 & K914090 respectively).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

St. Jude Medical
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NOV - 4 2009

Re: K093130
Engage™ TR Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 2, 2009
Received: October 5, 2009

Dear Ms. Pham:

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.

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,

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

Enclosure

Section 3. Indication For Use

510(k) Number: K093130

Device Name: Engage™ TR Introducer

Indication for Use:

The introduction of angiographic catheters, closed end catheters, balloon catheters, and electrodes into a blood vessel (including but not limited to femoral, radial, and brachial access) where minimizing blood loss is essential.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

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