K073563

Section 5. 510(k) Summary

5.1 Applicant Information

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

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Date Prepared: 17 December, 2007

5.2 Device Information

Trade Name:	Proxis System
Common Name:	Proximal Embolic Protection Device
Classification Name:	Device, coronary saphenous vein bypass graft, temporary, for embolization protection
Classification:	Class II per 21 CFR 870.1250
Product Code:	NFA

5.3 Device Description

The Proxis System (Proxis Embolic Protection System) is a proximal embolic protection system used in conjunction with other interventional devices. The Proxis System protects the patient from distal embolization by preventing antegrade flow of emboli release during an interventional procedure and then removing it from the vessel. The Proxis System consists of an Evacuation Sheath Catheter (Proxis Catheter), Inflation device, Aspiration syringe, Lip Seal and Strainer

basket. In addition, an optional accessory called the Proxis Infusion Catheter (packaged separately) may be used with Proxis System.

In the stagnant flow, the guide wire is advanced across the lesion site and the interventional device is tracked over the guide wire. Upon completion of the interventional device procedure, fluid and particles from the procedure may be aspirated using the aspiration syringe. If there is insufficient venous or collateral flow, the Proxis Infusion Catheter (optional accessory) may be used to deliver saline distal to the treatment site while simultaneously applying vacuum to aspirate fluid and particles from the treatment site.

5.4 Intended Use

There is no change to the intended use of the modified Proxis System as it is identical to the predicate Proxis System, K052523-Sept. 7, 2006.

The Proxis System is indicated for use as a proximal embolic protection system to prevent distal release of and to aspirate embolic material (thrombus/debris) in saphenous vein coronary bypass graft(s) (3.0 mm – 5.0 mm) during percutaneous transluminal coronary angioplasty and/or stenting procedures.

The Proxis System is also indicated to control the flow of fluids and aid in the removal of fresh, soft emboli and thrombi in the coronary and peripheral vasculature.

The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature; native coronary arteries; or for treatment of patients with acute myocardial infarction. The device is not intended to be used as a thrombectomy system.

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5.5 Predicate Device Comparison/Technological Characteristics

The Proxis System included in this Special 510(k) submission shares the same intended use as the predicate Proxis System (K052523, *Sept. 7, 2006*), which is indicated for embolic protection, control of flow of fluids, and aid in the removal of fresh soft thrombi and emboli. The modified Proxis System is physically identical to the cleared Proxis System (K060651, *Sept. 13, 2006*)), with the exception of a non-significant change in material for the occluding balloon. In addition, a precaution statement was added to the Instructions for Use to alert users of the risk of applying excessive pressure to the Proxis System.

The modifications to the Proxis System do not affect the intended use of the system and there is no alteration in the fundamental scientific technology of the device. The Proxis System covered by this Special 510(k) submission is identical in function, technological characteristics, mechanism of action and intended use as the market cleared predicated devices, Proxis System (K060651 & K052523).

5.6 Test Summary

The Proxis System passed all verification specification criteria for dimensional, strength, functional, packaging, sterilization, biocompatibility, and shelf life tests as cleared in K060651. Previously reviewed test results (K060651 and K052523) confirm the device performs as intended without raising additional questions of safety and efficacy. Given the scope of the modifications incorporated to create the proposed Proxis System, no additional animal or clinical data was deemed necessary.

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5.7 Substantial Equivalence

The Proxis System covered by this submission is substantially equivalent to the previously cleared Proxis Systems, K060651 and K052523, given identical technological characteristics, principles of operation and intended use.

5.8 Conclusion

The Proxis System in this submission has the same indications for use (K052523), principles of operation (K052523 & K060651), and technological characteristics (K060651) as the previously cleared predicate devices.

As a result, the differences between this device and its predicate devices do not raise new questions of safety or efficacy. Therefore, the Proxis System is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

St. Jude Medical
c/o Ms. Linh Pham
Regulatory Affairs Specialist
6500 Wedgwood Road North
Maple Grove, MN 55311

Re: K073563
Trade Name: Proxis™ System
Regulation Number: 21 CFR 870.1250
Regulation Name: Proximal Emblic Protection Device
Regulatory Class: Class II
Product Code: NFA
Dated: January 25, 2008
Received: January 28, 2008

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachuer

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

Enclosure

Section 4. Indication For Use

510(k) Number: K073563

Device Name: Proxis System

Indication for Use:

The Proxis System is indicated for use as a proximal embolic protection system to prevent distal release of and to aspirate embolic material (thrombus/debris) in saphenous vein coronary bypass graft(s) (3.0 mm – 5.0 mm) during percutaneous transluminal coronary angioplasty and/or stenting procedures.

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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. Vochner

(Division Sign-Off)
Division of Cardiovascular Devices

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