K073700

Section 5. 510(k) Summary

5.1 Applicant Information

Submitted by: St. Jude Medical
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OCT - 2 2008

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Date Prepared: 28 December, 2007

5.2 Device Information

Trade Name:	6F Proxis™ System
Classification Name:	Percutaneous Catheter
Classification:	Class II per 21 CFR 870.1250
Product Code:	DQY

5.3 Device Description

The 6F Proxis System (Proxis System) is a proximal flow control system used in conjunction with other interventional devices. The Proxis System controls the flow of fluids in the coronary and peripheral vasculature. This is achieved by temporarily occluding the vessel which holds the column of fluid stagnant. The stagnant column can be used to aid in the visualization of the lesion and for the delivery of therapeutic solution(s).

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.

The Proxis Catheter is loaded onto the guide wire and tracked down to the distal portion of the guide catheter and proximal to the lesion. To minimize the occlusion time, the interventional devices are advanced through the Proxis Catheter and positioned near the distal tip. When the sealing balloon is inflated, antegrade flow of the fluid in the target vessel is prevented.

While the vessel is occluded, therapeutic solutions may be infused through the Proxis Catheter and stagnated in the target vessel/lesion during the delivery of the therapeutic device or after the deployment of the therapeutic device.

The aspiration syringe is provided for the removal of stagnated fluid and/or fresh, soft thrombi and emboli during aspiration. Additionally, if there is insufficient venous or collateral flow, the Proxis Infusion Catheter (optional accessory) may be used to infuse saline to augment the retrograde flow of fluid and removal of stagnated fluid.

5.4 Intended Use

The 6F Proxis System controls the flow of fluids in the coronary and peripheral vasculature. This is achieved by temporary vessel occlusion to hold a column of fluid in the vessel stagnant. The stagnant column can be used to aid in the visualization of the lesion or be used as a means of local and temporary delivery of therapeutic solutions.

The 6F Proxis System is also indicated for use as an aid in the removal of fresh, soft emboli and thrombi in the coronary and peripheral vasculature.

The safety and efficacy of this device as an embolic protection system has not been established. The 6F Proxis System is not indicated for use for embolic protection. The device is not intended to be used as a thrombectomy system.

5.5 Test Summary

The Proxis System passed all verification specification criteria for dimensional, strength, functional, packaging, sterilization, biocompatibility, and shelf life tests as cleared in K063638. Previously reviewed test results (K063638 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 Proxis System, no additional animal or clinical data was deemed necessary.

5.6 Substantial Equivalence

The Proxis System covered by this submission is substantially equivalent to the previously cleared Proxis System (K063638) and Proxis Flow Control System (K052523) given identical technological characteristics and principles of operation and similar intended uses (control of flow of fluids and aid in fresh, soft thrombus removal).

5.7 Conclusion

The Proxis System in this submission has similar indications for use—control of flow of fluids and aid in soft thrombus removal—(K052523), identical principles of operation (K063638) and technological characteristics (K063638) 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

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

OCT - 2

Re: K073700
Trade/Device Name: 6F Proxis™ System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 30, 2008
Received: October 1, 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's) 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,

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: K073700

Device Name: 6F Proxis™ System

Indication for Use:

The 6F Proxis System controls the flow of fluids in the coronary and peripheral vasculature. This is achieved by temporary vessel occlusion to hold a column of fluid in the vessel stagnant. The stagnant column can be used to aid in the visualization of the lesion or be used as a means of local and temporary delivery of therapeutic solutions.

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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. Jackson

(Division Sign-Off)
Division of Cardiovascular Devices

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