K083833

510(k) SUMMARY

EndoCross's ENABLER-P Catheter

Applicant's Information

Date Prepared:	December 23, 2008
Name and Address:	EndoCross Ltd New Industrial Park, Building 7 P.O.B 620, Yoqneam 20692, Israel
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MAY 22 2009

Device Information

Classification:	DQY
Trade Name:	ENABLER-P Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, DQY / 21 CFR 870.1250

Predicate Devices

- ENABLER-P Support Catheter manufactured by Endocross (K082339)
- Asahi Tornus Support Catheter manufactured by Asahi Intecc (K051772)

Intended Use / Indications for Use

The ENABLER-P Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.

Technological Characteristics

The ENABLER-P Catheter is a dual-lumen intravascular catheter intended for percutaneous use. It is designed for use in conjunction with a 0.035" guidewire to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guidewires may be exchanged within the catheter. In addition, the ENABLER-P Catheter can provide distal anchoring and support the advancement of the guidewire.

The ENABLER-P Catheter is packaged in a Tyvek/Poly pouch to form a sterile barrier. The packaged catheter is sterilized by ethylene oxide gas. The ENABLER-P Catheter is provided "STERILE" and "Non-pyrogenic", and is intended for single use only.

The ENABLER-P Catheter is similar in basic materials, design, construction and mechanical performance to a combination of the predicate devices.

Biocompatibility And Performance Data

Biocompatibility testing, in vitro bench studies and animal studies were conducted to evaluate the biological and performance characteristics of the ENABLER-P Catheter. Biocompatibility test results indicate that the device materials are biocompatible. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

Substantial Equivalence

The ENABLER-P Catheter is substantially equivalent to the ENABLER-P Support Catheter manufactured by EndoCross and the Asahi Tornus Support Catheter manufactured by Asahi Intecc.

The ENABLER-P Catheter has the same intended use as the ENABLER-P Support Catheter and the Asahi Tornus Support Catheter and identical technological characteristics as the ENABLER-P Support Catheter. Performance data demonstrate that the ENABLER-P Catheter is substantially equivalent to the ENABLER-P Support Catheter and the Asahi Tornus Support Catheter..

Thus, the ENABLER-P Catheter is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

EndoCross, Ltd.
c/o John J. Smith, M.D., J.D.
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street N.W.
Washington, D.C. 20004

Re: K083833
Trade/Device Name: ENABLER-P Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: April 10, 2009
Received: April 10, 2009

Dear Dr. Smith:

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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

Indications for Use Statement

510(k) Number (if known): K083833

Device Name: ENABLER-P Catheter

Intended Use / Indications for Use:

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Prescription Use ___√___ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 C.F.R. 807 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 K083833