1092174

510(k) SUMMARY

EndoCross's ENABLER-P Catheter System

Applicant's Information

DEC 30 2009

Date Prepared:	July 17, 2009
Name and Address:	EndoCross Ltd New Industrial Park, Building 7 P.O.B 620, Yoqneam 20692, Israel
Contact Person:	Yaron Eshel Tel: + 972-4-9090030 Fax: + 972-4-9090055

Device Information

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

Predicate Devices

- ENABLER-P Catheter manufactured by Endocross (K082339, K083833)
- Metricath System manufactured by Angiometrx Inc (K024000)
- Everest 20cc Inflation Device manufactured by Medtronic (K942269)

Intended Use / Indications for Use

The ENABLER-P Catheter System 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 System is comprised of the ENABLER-P Catheter, the ENABLER Pressure Control Unit (PCU), and accessories including a sterile cover, syringe, manifold and extension tube.

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, using a distal balloon, 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 Pressure Control Unit (PCU) an optional accessory used to automate the inflation and deflation of the catheter's balloon. The PCU is single use and supplied non sterile with a specially designed sterile cover to allow proper use in sterile areas.

Biocompatibility And Performance Data

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

Substantial Equivalence

The ENABLER-P Catheter System is substantially equivalent to the cleared ENABLER-P Catheter manufactured by EndoCross, the Medtronic Everest 20cc Inflation Device and the Angiometrx Metricath System.

The ENABLER-P Catheter System has the same intended use as the cleared ENABLER-P Catheter and similar technological characteristics as the cleared ENABLER-P Catheter, the Medtronic Everest 20cc Inflation Device and the Angiometrx Inc., Metricath System. Any differences in technological characteristics or principles do not raise new questions of safety or efficacy.

Thus, the ENABLER-P Catheter System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

DEC 30 2009

Re: K092174
Trade/Device Name: ENABLER-P Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 22, 2009
Received: December 22, 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.

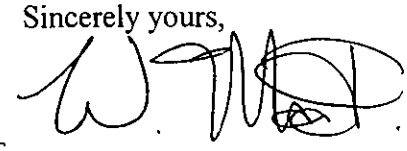
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 (240) 276-3150 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

Indications for Use Statement

510(k) Number (if known): K092174

Device Name: ENABLER-P Catheter System

Intended Use / Indications for Use:

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

Prescription Use ___√___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (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)

Page 1 of 1

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K092174