510 (k) SUMMARY

AUG 25 2010

Applicant

ThermopeutiX, Inc.
9925B Businesspark Avenue
San Diego, California 92131
Phone: (858) 549-1760
Fax: (858) 549-1717

Manufacturer

ThermopeutiX, Inc.
9925B Businesspark Avenue
San Diego, California 92131
Phone: (858) 549-1760
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Contact Person

Thomas Schroeder, Director, RA/QA

Common Names: Temporary Intravascular Occluding Catheter

Classification Name: Devices of this type are classified as Class II under 21 CFR Part CFR Part 870.4450, Vascular Clamp (Product Code MJN).

Proprietary Name: DuoFlo™ Catheter (Heparin Coated)

Predicate Devices

The ThermopeutiX DuoFlo™ Catheter (Heparin Coated) is substantially equivalent in indications, design, construction and features to the ThermopeutiX DuoFlo™ catheter cleared under 510k K080700 with the exception that bound heparin has been included in the catheter's hydrophilic coating..

Indications for Use

There is no change in the indications for use for the DuoFlo™ Catheter (Heparin Coated). The existing DuoFlo™ catheter indications statement remains unchanged.

Device Description

The DuoFlo™ Catheter is a sterile single use device that consists of concentric shafts with four lumens with access via Luer connectors as follows, one for balloon inflation, one for pressure monitoring and two concentric lumens for infusate injection or extracorporeal circuit connections. The central through lumen accepts up to a 0.038" guidewire.

Technological Characteristics Comparison

The DuoFlo™ Catheter identical in design and construction to the currently marketed DuoFlo™ catheter with the exception that bound heparin has been included in the catheter coating. The heparin in the coating helps to minimize thrombus formation on the catheter surfaces.

Performance and Safety

The biological safety of the device has been demonstrated through biocompatibility studies of patient contact materials in accordance with the standards outlined in ISO 10993-1.

The device is supplied sterile and sterility conforms to a Sterility Assurance Level (SAL) of 10^{-6}. The supplied instructions for use provide the user with the applicable warnings and cautions during use. There are no new safety or effectiveness issues related to this device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ThermopeutiX, Inc
c/o Mr. Thomas Schroeder
Director, RA/QA
9925B Businesspark Avenue
San Diego, CA 92131

AUG 25 2010

Re: K093847
Trade/Device Name: DuoFlo Catheter (Heparin Coated)
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: MJN
Dated: July 22, 2010
Received: July 26, 2010

Dear Mr. Schroeder:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

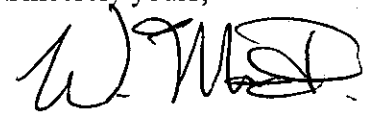
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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 K093847

Device Name: DuoFlo™ Catheter and DuoFlo™ Catheter (Heparin Coated)

Indications for use: The DuoFlo™ Catheter is intended for general intravascular use in the peripheral vasculature in arteries 3.5 mm and larger. Once placed in the selected region, the catheter can be used for infusion of diagnostic and/or therapeutic agents, and for controlling blood flow to the selected region when connected to an extracorporeal circuit. The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer.

The DuoFlo™ Catheter is contraindicated for use in the coronary and intracranial arteries.

The DuoFlo™ Catheter is not intended for embolic protection or as an aspiration catheter.

Prescription Use: ____X____ AND/OR Over-the-counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K093847