K080700

SEP 2 6 2008

ThermopeutiX, Inc.
September 25, 2008

510 (k) SUMMARY

Applicant

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

Manufacturer

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

Contact Person

Thomas Schroeder, Director, RA/QA

Common Names: Temporary Intravascular Occluding Catheter
Diagnostic Intravascular Catheter

Classification Names: Devices of this type are classified as Class II under 21 CFR Part 870.1200, Diagnostic Intravascular Catheter (Product Code DQO) and 21 CFR Part 870.4450, Vascular Clamp (Product Codes MJN and DXC).

Proprietary name: DuoFlo™ Catheter

Predicate Devices

The ThermopeutiX DuoFlo™ is substantially equivalent in general indications and design and features to temporary occluding catheters, perfusion catheters and diagnostic intravascular catheters; these devices are:

1) OriGen Dual Lumen Catheter (K003288) – DQO
2) Coaxia FloControl™ Catheter (K023914) – MJN
3) Estech Remote Access Perfusion Catheter (K990573) – DXC

510 (k) SUMMARY

Indications for Use

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 Duo-Flo Catheter is contraindicated for use in the coronary and intracranial arteries.

The Duo-Flo Catheter is not intended for embolic protection or as an aspiration catheter.

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 catheter is equivalent in design and construction to currently marketed temporary occluding catheters and intravascular continuous flush catheters. The construction materials used have an established history of safe use in similar medical devices.

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. Physical testing was performed to assure catheter integrity including verification of catheter body and balloon burst pressure.

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
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

ThermopeutiX, Inc.
c/o Ms. Dawn Tibodeau
Project Coordinator
TUV SUD America Inc.
1775 Old Hwy 8 NW, Ste 104
New Brighton, MN 55112-1891

Re: K080700
Trade/Device Name: DuoFlo™ Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: September 9, 2008
Received: September 10, 2008

Dear Ms. Tibodeau:

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,

Donna R. Vachner

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): K080700

Device Name: DuoFlo™ Catheter

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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)

Donna R. Vochniak

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080700