510 (k) SUMMARY

Applicant

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Manufacturer

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SEP 2 6 2013

Contact Person

Jason Ford, Quality Assurance

Common Names: Support Catheter

Classification Name: Devices of this type are classified as Class II under 21 CFR Part CFR Part 870.1250, Percutaneous Catheter (Product Code DQY).

Proprietary Name: Primi™ Support Catheter

Predicate Devices

The ThermopeutiX Primi™ Support Catheter with the advanced hydrophilic coating is substantially equivalent in indications, design, construction and features to the ThermopeutiX Primi™ Support Catheter cleared under 510(k) K130850 with the exception of the hydrophilic coating.

Indications for Use

There is no change in the indications for use for the Primi™ Support Catheter with the advanced hydrophilic coating. The existing Primi™ Support Catheter indications statement remains unchanged. The indications for use are as follows:

The Primi™ Support Catheter is intended to be used in conjunction with guidewires in order to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The support catheter also may be used to selectively infuse/deliver physician specified diagnostic and/or therapeutic agents, such as sterile saline, contrast agents, vaso-dilators, anti-blastics, lytics, and anti-thrombotics, with or without a guidewire in position.

Device Description

The ThermopeutiX Support Catheter that is the subject of this submission is a single lumen catheter with a radiopaque marker that aids in positioning the catheter and a tapered tip to facilitate entry. The catheter utilizes an integral spine wire. The catheter is available in several diameters and lengths which are 0.014", 0.018", or 0.035" guidewire compatible. The working lengths are 90 cm thru 170 cm. Reference Table 1 for model number availability. The distal portion of the catheter shaft has a hydrophilic coating to facilitate insertion. The device has a luer hub connector to allow infusion of diagnostic and/or therapeutic agents. The device is supplied sterile and is intended for single use only. Reference Table 2 below for physical and performance characteristics.

Table 1- Model Numbers for the Primi™ Support Catheter with the advanced hydrophilic coating

PU14 -20-90	PU14 -40-90	PU14 -60-90	PU14 -80-90	PU14 -100-90	PU14 -120-90
PU14 -20-90HF	PU14 -40-90HF	PU14 -60-90HF	PU14 -80-90HF	PU14 -100-90HF	PU14 -120-90HF
PU18-20-90	PU18-40-90	PU18-60-90	PU18-80-90	PU18-100-90	PU18-120-90
PU35-20-90	PU35-40-90	PU35-60-90	PU35-80-90	PU35-100-90	PU35-120-90
PU14 -20-130	PU14 -40-130	PU14 -60-130	PU14 -80-130	PU14 -100-130	PU14 -120-130
PU14 -20-130HF	PU14 -40-130HF	PU14 -60-130HF	PU14 -80-130HF	PU14 -100-130HF	PU14 -120-130HF
PU18-20-130	PU18-40-130	PU18-60-130	PU18-80-130	PU18-100-130	PU18-120-130
PU35-20-130	PU35-40-130	PU35-60-130	PU35-80-130	PU35-100-130	PU35-120-130
PU14 -20-150	PU14 -40-150	PU14 -60-150	PU14 -80-150	PU14 -100-150	PU14 -120-150
PU14 -20-150HF	PU14 -40-150HF	PU14 -60-150HF	PU14 -80-150HF	PU14 -100-150HF	PU14 -120-150HF
PU18-20-150	PU18-40-150	PU18-60-150	PU18-80-150	PU18-100-150	PU18-120-150
PU35-20-150	PU35-40-150	PU35-60-150	PU35-80-150	PU35-100-150	PU35-120-150
PU14 -20-170	PU14 -40-170	PU14 -60-170	PU14 -80-170	PU14 -100-170	PU14 -120-170
PU14 -20-170HF	PU14 -40-170HF	PU14 -60-170HF	PU14 -80-170HF	PU14 -100-170HF	PU14 -120-170HF
PU18-20-170	PU18-40-170	PU18-60-170	PU18-80-170	PU18-100-170	PU18-120-170
PU35-20-170	PU35-40-170	PU35-60-170	PU35-80-170	PU35-100-170	PU35-120-170

* The HF suffix indicates the high flow version
PUxx-yy-zzz, xx=guide wire size (0.014", 0.018", or 0.035")
yy=distal shaft length (20mm, 40mm, 60mm, 80mm, 100mm, or 120mm)
zzz=Overall catheter length (150cm or 170cm)

Table 2-Physical and Performance Characteristics

Element/Feature	ThermopeutiX Primi Support Catheters
Working Length (s)	90 cm – 170 cm; polymer shaft with integral spine wire
Distal Shaft Length (mm)	20, 40, 60, 80, 100, 120
Outside Diameter (s)	Distal:0.045" – 0.064" Proximal: 0.060" – 0.080"
Lumen	One
Guide wire Compatibility	0.014" – 0.035"
Distal End Configuration	Tapered tip for ease of crossing
Fluid connection	Luer hub connector
Flow rate @ 150 psi	0.014" wire models > 0.80 cc/sec, Saline 0.035" wire models > 0.50 cc/sec, Saline 0.014" wire models > 0.30 cc/sec, Contrast 0.035 wire models > 0.15 cc/sec, Contrast
Maximum Injection Pressure	300 psi
Hydrophilic Coating	Yes; distal portion, for lubricity
Radiopaque Markers	One
Sheath Compatibility	5 Fr and 6 Fr
Catheter Materials	Hub-Pebax Outer Shaft-Pebax Inner Shaft-HDPE Distal Shaft-Pebax w/radiopaque filler Core Wire-Stainless Steel tapered wire Coating-Hydrophilic proprietary coating

Technological Characteristics Comparison

The Primi™ Support Catheter with the advanced hydrophilic coating is identical in design and construction to the currently marketed Primi™ Support Catheter with the exception of the hydrophilic coating. The advanced hydrophilic coating provides comparable lubricity with a reduction in particulates. The coating is applied to the same portion of the candidate device as the predicate device. The coating thickness is considered equivalent between the candidate and predicate device.

Table 3-Predicate Device Characteristics Comparison

Element/Feature	ThermopeutiX Primi Support Catheter (This 510k)	ThermopeutiX Primi Support Catheter 510(k) K130850
Working Length (s)	90 cm – 170 cm; polymer shaft with integral spine wire	90 cm – 170 cm; polymer shaft with integral spine wire
Outside Diameter (s)	Distal:0.045" – 0.064" Proximal: 0.060" – 0.080"	Distal:0.045" – 0.064" Proximal: 0.060" – 0.080"
Lumen	One	One
Guide wire Compatibility	0.014" – 0.035"	0.014" – 0.035"
Guide wire Use	Over the Wire	Over the Wire
Distal End Configuration	Tapered tip for ease of crossing	Tapered tip for ease of crossing
Fluid connection	Luer hub connector	Luer hub connector
Flow rate @ 150 psi w/Saline	0.014" wire models > 0.80 cc/sec 0.035" wire models > 0.50 cc/sec	0.014" wire models > 0.80 cc/sec 0.035" wire models > 0.50 cc/sec
Flow rate @ 150 psi w/Contrast	0.014" wire models > 0.30 cc/sec 0.035" wire models > 0.15 cc/sec	0.014" wire models > 0.30 cc/sec 0.035" wire models > 0.15 cc/sec
Maximum Injection Pressure	Do not exceed 300 psi	Do not exceed 300 psi
Coating	Yes; advanced hydrophilic, distal portion	Yes; hydrophilic, distal portion
Coating Length	65 cm, 115 cm or 140 cm (lengths are the same as the predicate across all models)	65 cm, 115 cm or 140 cm
Coating Thickness	Same as predicate	Proprietary
Radiopaque Markers	One	One
Sheath Compatibility	5 Fr and 6 Fr	5 Fr and 6 Fr
Materials Used	Hub-Pebax Outer Shaft-Pebax Inner Shaft-HDPE Distal Shaft-Pebax w/radiopaque filler Core Wire-Stainless Steel tapered wire Coating-Advanced hydrophilic proprietary coating Marker Band-Platinum/Iridium	Hub-Pebax Outer Shaft-Pebax Inner Shaft-HDPE Distal Shaft-Pebax w/radiopaque filler Core Wire-Stainless Steel tapered wire Coating-Hydrophilic proprietary coating Marker Band-Platinum/Iridium

Non-Clinical Tests

The non-clinical tests performed on sample devices are listed below. All testing passed internal protocol requirements and met product specifications. All of the requirements in the standards utilized were met.

-Biocompatibility Testing (ISO10993-1)
- -Cytotoxicity (ISO 10993-5)
- -Sensitization (Guinea Pig Maximization ISO 10993-10)
- -Irritation (ISO 10993-10)
- -Systemic Toxicity (ISO 10993-11)
- -Complement Activation (C3a and SC5b-9 ISO10993-4)
- -Pyrogen (ISO 10993-11)
- -Hemocompatibility (Hemolysis, Thromboresistance, Partial Thromboplastin Time (ISO 10993-4 and ASTM F2382)

-Device Functional Testing
- -Dimensional
- -Wire Movement/Compatibility
- -Catheter Torque
- -Catheter Kink
- -Hub Leakage
- -Peripheral Model Passage
- -Coating Particulate
- -Coating Durability/Integrity
- -Radiopacity
- -Maximum Injection Pressure
- -Flow Rate Testing (wire in/wire out)
- -Tensile Test (distal tip, distal tip to wire, distal shaft to proximal shaft, hub to shaft)
- -Pouch Seal Integrity
- -All performance testing was repeated on samples with a minimum of 10 month aging.

Conclusion

Based on the non-clinical testing results, the Primi™ Support Catheters with the advanced hydrophilic coating are substantially equivalent to the legally marketed device identified in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 26, 2013

Thermopeutix, Inc.
Mr. Jason Ford
Quality Engineer
9951B Businesspark Avenue
San Diego, CA 92131

Re: K132701
Trade/Device Name: Primi™ Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: July 30, 2013
Received: August 29, 2013

Dear Mr. Ford:

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 contact 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. 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,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (If Known): _____

Device Name: Primi™ Support Catheter

Indications For Use:

The Primi™ Support Catheter is intended to be used in conjunction with guidewires in order to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The support catheter also may be used to selectively infuse/deliver physician specified diagnostic and/or therapeutic agents, such as sterile saline, contrast agents, vaso-dilators, anti-blastics, lytics, and anti-thrombotics, with or without a guidewire in position.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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