K101117

6.0 510(k) Summary

6.1 Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. E.
Mississauga, Ontario
Canada
L4W 5S4

JUL 16 2010

C. Company Phone: (905) 602-4875

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: July 14, 2010

6.2 Device Identification

A. Device Trade Name: Lev-OR™ Dilation Catheter OTW

B. Device Common Name: Lev-OR™ Dilation Catheter OTW

C. Classification Name: Percutaneous Catheter (21 CFR 870.1250)

D. Device Class: II

E. Device Code: DQY

6.3 Identification of Predicate Device

Predicate devices are:

- Skyway Support Catheter (K060327) by Vascular Solutions, Inc.
- Gopher Support Catheter (K070372) by Vascular Solutions, Inc.

6.4 Device Description

The Lev-OR™ Dilation Catheters OTW is a family of intravascular catheters each with a shaft designed for use in the peripheral vasculature. The lumen in the catheter permits the use of a guidewire to facilitate advancement of the catheter to and through the lesion to be treated.

The different models of the Lev-OR™ Dilation Catheter OTW (herein referred to as "Catheter") have varying distal section stiffnesses. The model can be identified by the printed label on the device packaging.

The Catheter body low profile and gentle taper facilitate smooth advancement through target locations such as complex lesions. The distal 25cm of the catheter, treated with a lubricious hydrophilic coating, is activated when wet.

The Catheter has a radiopaque distal tip and can accommodate a range of 0.014" – 0.035" diameter guidwires depending on the model.

A standard female luer connector at the proximal end provides fluid injection capabilities.

Depending on the model, the Catheter is intended to be used in conjunction with 0.014" - 0.035" guidewires or Baylis Medical RF PowerWire™ during percutaneous transluminal angioplasty (PTA).

6.5 Intended Use

The Lev-OR™ Dilation Catheter OTW is used to access discrete regions of the peripheral vasculature. It may be used to facilitate the placement and exchange of guidewires and other interventional devices and may be used for the infusion or delivery of diagnostic and/or therapeutic agents.

6.6 Substantial Equivalence

This device is substantially equivalent to predicate devices with respect to fundamental scientific technology. This determination is based upon results from performance tests as listed below:

Biocompatibility:

1. Cytotoxicity
2. Sensitization
3. Irritation or Intracutaneous reactivity
4. Systemic toxicity (acute)

5. Haemocompatibility

The results of these tests demonstrate that the materials used to construct the Lev-OR Dilation Catheter OTW are safe for the intended use of the product.

Sterlization Validation was conducted as per ANSI/AAMI/ISO 11135:2007 and FDA Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test. Ethylene Oxide residue levels are in compliance with ISO 10993-7:2008.

Mechanical Testing:

- Flow Rate Measurement
- Freedom from Liquid Leakage
- Burst Pressure
- Freedom from Air Leakage
- Force at break / distal tip integrity
- Force at break – tensile - proximal hub
- Torsion

Other General Physical Tests:

- Corrosion Resistance testing demonstrated that the Lev-OR Dilation Catheter OTW did not exhibit signs of corrosion.

Bench Top Study:

- Device Compatibility
- Smooth Tracking
- Radiopacity
- Overall Length
- Ease of Use
- Dilation of channel/Pushability
- Fluid delivery
- Intended Use
- Reinsertion
- Coating Durability

The results of the bench top study indicate that the above attributes of the Lev-OR Dilation Catheter OTW are acceptable for the intended use of the device.

Packaging Testing was conducted as per ANSI/AAMI/ISO 11607:2006.

The results of these tests demonstrate that this device is safe and effective and performs as per the intended use.

The data and information presented in this application (including biocompatibility tests, sterilization validation, mechanical testing, bench top model testing, general physical testing, packaging testing, and device similarities) support a determination of substantial equivalence and, therefore, the market clearance of the Lev-OR Dilation Catheter OTW through this 510(k) Premarket Notification.

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

JUL 16 2010

Baylis Medical Co., Inc.
c/o Ms. Meghal Khakhar
Manager, Regulatory and Scientific Affairs
2645 Matheson Blvd. E
Mississauga, Ontario, Canada L4W 5S4

Re: K101117
Trade/Device Name: Lev-OR Dilation Catheter OTW
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: July 6, 2010
Received: July 8, 2010

Dear Ms. Khakhar

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K101117

Device Name: Lev-OR™ Dilation Catheter OTW

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101117