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6. 510(k) Summary

General Information

Date Compiled	December 12, 2013
Classification	Class III, 21 CFR § 876.5540, Blood Access Devices and Accessories, Product code MSD (Catheter, Hemodialysis, Implanted)
Trade Name	NexSite™ HD, Hemodialysis Catheter for long term use
Model Numbers	NEXHD1553201: NexSite HD, Hemodialysis Catheter for long term use (32 cm) NEXHD1553601: NexSite HD, Hemodialysis Catheter for long term use (36 cm) NEXHD1554001: NexSite HD, Hemodialysis Catheter for long term use (40 cm)
Submitter	Marvao Medical Devices, Ltd. GMIT Innovation in Business Centre, Dublin Road Galway, Ireland
Contact	Christine Nichols RAC Boston Biomedical Associates 386 West Main Street, Suite 7 Northborough, MA 01532 Phone: (508) 351-8632 ext 252 Fax: (508) 351-8637

Intended Use

Indicated for use in attaining long term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily inserted in the internal jugular vein of an adult patient. Alternate insertion sites include the subclavian vein.

Predicate Devices

K121933
Marvao NexSite HD Hemodialysis Catheter for long term use (24cm and 28cm lengths)
Manufactured by Marvao Medical Devices Ltd.

Device Description

The Modified NexSite HD Hemodialysis Catheter for long term use is intended for use in attaining long term vascular access for hemodialysis and apheresis. The polyurethane catheter has a Dacron cuff distal to the bifurcation hub. A Polyurethane/Dacron Dermal Ingrowth Support Collar (DISC) supplied with the Catheter is implanted subcutaneously, and is intended to assist with the direction of the catheter. The catheter is provided in three catheter lengths (32cm, 36cm and 40cm). The Catheter and DISC are packaged with accessories (stainless steel Tunneler and Sleeve, 0.038" Guidewire, 16Fr Introducer/Dilator, Coring Scalpel and Luer Caps) that are used to facilitate catheter placement.

The Modified NexSite HD, Hemodialysis Catheter for long term use is provided as a sterile, single-use device, and is sterilized using a validated ethylene oxide process. The Modified NexSite HD Hemodialysis Catheter for long term use is a blood contact device with greater than 30 days of exposure.

Comparison to Predicate Devices

Comparison testing was performed on pre-defined characteristics using proposed finished NexSite™ HD devices and commercial predicate devices (K121933). The test results support the substantial equivalence of the Modified NexSite™ HD device to the predicate devices.

Testing

Performance testing was performed on the predicate NexSite HD, Hemodialysis Catheter for long term use to assure reliable design and performance in accordance with ISO 10555-1. The materials and manufacturing processes used in the manufacture of the Modified NexSite HD catheters are identical to those used in the manufacture of cleared NexSite HD devices (K121933). Therefore most of the performance testing completed for the cleared NexSite HD catheters was applicable to the Modified NexSite HD catheters, and as such the testing was not repeated. The testing performed specifically on the proposed Modified NexSite HD catheters includes visual and dimensional analysis and pressure vs. flow testing. The test results demonstrate that the Modified NexSite™ HD, Catheter for long term use meets the requirements in the applicable standards and specifications, and is substantially equivalent to legally marketed predicate devices.

Guidance

The FDA *Guidance on Premarket Notification [(510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95, was utilized in order to meet the FDA requirements for content and organization of this submission, as well as the *Draft Guidance Industry and Food and Drug Administration Staff Implanted Blood Access Devices for Hemodialysis, June 28, 2013.*

Summary of Substantial Equivalence

Marvao Medical believes the Modified NexSite HD, Hemodialysis Catheter for long term use is substantially equivalent to the predicate NexSite HD Hemodialysis catheter (K121933). The indications for use, methods of operation, design and materials used are either identical or substantially equivalent to existing legally marketed predicate products.

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

January 31, 2014

Marvao Medical Devices, Ltd.
% Christine Nichols RAC
Regulatory Affairs Manager
Boston Biomedical Associates
386 West Main Street, Suite 7
Northborough, MA 01532

Re: K133796
Trade/Device Name: Modified NexSite™ HD Hemodialysis Catheter for Long Term Use
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: January 10, 2014
Received: January 13, 2014

Dear Christine Nichols,

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

5. Indications for Use Statement

510(k) Number (if known): K133796

Device Name: Modified NexSite™ HD Hemodialysis Catheter for Long Term Use

Indications for Use:

Indicated for use in attaining long term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily inserted in the internal jugular vein of an adult patient. Alternate insertion sites include the subclavian vein.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) Subpart C)

AND/OR

Over-The-Counter Use____ (Per 21 CFR 801

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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