MAR 14 2013

5. 510(k) Summary

General Information

Date Compiled March 13, 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	NEXHD1552801: NexSite HD, Hemodialysis Catheter for long term use (2 cm) NEXHD1552401: NexSite HD, Hemodialysis Catheter for long term use (24 cm)
Submitter	Marvao Medical Devices, Ltd. GMIT Innovation in Business Centre, Dublin Road Galway, Ireland
Contact	Marybeth Gamber Boston Biomedical Associates 386 West Main Street, Suite 7 Northborough, MA 01532 Phone: (508) 351-8632 ext 206 Fax: (508) 351-8637

Intended Use

The NexSite HD, Hemodialysis Catheter for long term use is 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

Medcomp® Hemo-Flow® Long Term Hemodialysis Catheter Manufactured by Medcomp	K994105
Marvao NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter Manufactured by Marvao Medical Devices, Ltd.	K110627

Device Description

The NexSite HD, Hemodialysis Catheter for long term use is a long term catheter intended for use in attaining long term vascular access for hemodialysis and apheresis. The polyurethane NexSite HD, Hemodialysis Catheter for long term use is available in two lengths, 24cm and 28cm, and 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 minimize Catheter movement. 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 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 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 finished NexSite™ HD devices and commercial predicate devices (K994105 and K110627). The test results support the substantial equivalence of the NexSite™ HD device to the predicate devices.

Testing

In vitro testing was performed on the NexSite HD, Hemodialysis Catheter for long term use to assure reliable design and performance in accordance with ISO 10555-1:2004. The non-clinical tests performed include visual and dimensional, catheter leakage, catheter joint strength, catheter pressure, catheter flow rate testing, catheter recirculation testing, radiopacity and corrosion resistance. The test results demonstrate that the NexSite™ HD, Hemodialysis Catheter for long-term use meets the requirements in the applicable standards and specifications, and is substantially equivalent to legally marketed predicate devices.

In vivo implantation studies were also performed to demonstrate that the device would perform as intended. Clinical studies were not deemed necessary since *in vivo* and *in vitro* testing were sufficient to demonstrate safety and effectiveness by way of comparison to a legally marketed predicate device.

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.

Summary of Substantial Equivalence

Marvao Medical believes the NexSite HD, Hemodialysis Catheter for long term use is substantially equivalent to the predicate products. 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

March 14, 2013

Marvao Medical Devices, Ltd.
% Ms. Marybeth Gamber
Consultant
Boston Biomedical Associates, LLC
386 West Main Street, Suite 7
NORTHBOROUGH MA 01532

Re: K121933
Trade/Device Name: 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: March 6, 2013
Received: March 7, 2013

Dear Ms. Gamber:

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,

Elaine H. Blyskun -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

Enclosure

4. Indications for Use Statement

510(k) Number	K121933
Device Name:	NexSite™ HD, Hemodialysis Catheter for long term use
Indications for Use:	The NexSite HD, Hemodialysis Catheter for long term use is 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_ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 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)

Elaine H. Blyskun -S
for Benjamin Fisher

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121933