



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

August 8, 2016

Marvao Medical Devices, Ltd.  
% Joseph DePaolo  
Regulatory Manager  
Boston Biomedical Associates  
100 Crowley Drive, Suite 216  
Marlborough, MA 01752

Re: K161026  
Trade/Device Name: NexSite™ HD Hemodialysis Step Tip Catheter for long term use  
(24 cm, 28 cm, 32 cm, 36 cm, 40 cm, 55 cm)  
Regulation Number: 21 CFR§ 876.5540  
Regulation Name: Blood Access Device and Accessories  
Regulatory Class: II  
Product Code: MSD  
Dated: July 5, 2016  
Received: July 6, 2016

Dear Joseph DePaolo:

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/tray. 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

**Douglas Silverstein -S**  
2016.08.09 10:56:34 -04'00'

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

## Indications for Use

510(k) Number (if known)

K161026

Device Name

NexSite™ HD Hemodialysis Step Tip Catheter for long term use (24 cm, 28 cm, 32 cm, 36 cm, 40 cm, 55 cm)

Indications for Use (Describe)

The NexSite HD Hemodialysis Step Tip 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. Catheters greater than 40cm are indicated for femoral vein insertion.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21CFR Part 807.92.

### I. SUBMITTER

**Name:** Marvao Medical Devices, Ltd.

**Address:** GMIT Innovation in Business Centre, Dublin Road  
Galway, Ireland

**Phone:** +353 (0)91 759 301

**Fax:** +353 (0)91 762 055

**Contact Person:** Joseph DePaolo  
Boston Biomedical Associates  
386 West Main Street, Suite 7  
Northborough, MA 01532  
[jdepaolo@boston-biomedical.com](mailto:jdepaolo@boston-biomedical.com)  
Phone: (508) 691-7026  
Fax: (508) 351-8637

### II. DEVICE

**Device/Trade Name:** NexSite™ HD Hemodialysis **Step Tip** Catheter for long term use (24 cm, 28 cm, 32c m, 36 cm, 40 cm, 55 cm)

**Date of Preparation:** August 4, 2016

**Common Name:** Blood access devices and accessories

**Classification Name:** catheter, hemodialysis, implanted

**Classification Number:** 876.5540

**Product Code/ Classification Panel:** MSD/Gastroenterology /Urology

### III. PREDICATE DEVICE(S):

K121933 / K133796 /K140492 Marvao NexSite HD Hemodialysis Catheter for long term use, Manufactured by Marvao Medical Devices, Ltd.

K143567 Marvao NexSite HD Hemodialysis Split Tip Catheter for long term use, Manufactured by Marvao Medical Devices, Ltd.

#### IV. DEVICE DESCRIPTION

The proposed device, the NexSite HD Hemodialysis **Step Tip** Catheter for long term use is a long term catheter intended for use in attaining long term vascular access for hemodialysis and apheresis. The proposed device is available in the following models below and has a Dacron cuff distal to the bifurcation hub.

##### Models:

- NexSite HD Hemodialysis **Step Tip** Catheter for long term use (24cm)
- NexSite HD Hemodialysis **Step Tip** Catheter for long term use (28cm)
- NexSite HD Hemodialysis **Step Tip** Catheter for long term use (32cm)
- NexSite HD Hemodialysis **Step Tip** Catheter for long term use (36cm)
- NexSite HD Hemodialysis **Step Tip** Catheter for long term use (40cm)
- NexSite HD Hemodialysis **Step Tip** Catheter for long term use (55cm)

A Dermal Ingrowth Support Collar (DISC), manufactured from polyurethane and Dacron®. and supplied with the Catheter, is implanted subcutaneously, and is intended to assist with the direction of the catheter. The Catheter and DISC are packaged with accessories (stainless steel Tunneler and Sleeve, 0.038” Guidewire, 16Fr Introducer/Dilator, and Luer Caps) that are used to facilitate catheter placement.

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

#### V. INTENDED USE

The NexSite HD Hemodialysis **Step Tip** 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. Catheters greater than 40cm are indicated for femoral vein insertion.

#### VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The descriptive characteristics of the proposed device and the identified predicates were compared and determined to be substantially equivalent in terms of intended use, dimensions, materials, and basic design. Comparative performance testing using finished proposed NexSite™ HD **Step Tip** catheters and identified predicate devices was completed. The test results support the substantial equivalence of the proposed NexSite™ HD **Step Tip** catheter to the predicate devices.

#### VII. PERFORMANCE DATA

*In vitro* testing was performed on the NexSite HD Hemodialysis **Step Tip** Catheter to assure reliable design and performance in accordance with ISO 10555-1:2013.. The non-clinical tests performed include visual and dimensional, priming volume, catheter leakage, catheter joint strength, catheter pressure, catheter flow rate testing, catheter recirculation testing, catheter clamp

fatigue testing, mechanical hemolysis, chemical tolerance to disinfectant agents, radiopacity and corrosion resistance. The test results demonstrate that the NexSite™ HD Hemodialysis **Step Tip** Catheter 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, as well as the *t Guidance Industry and Food and Drug Administration Staff Implanted Blood Access Devices for Hemodialysis, January 21, 2016*.

#### VIII. CONCLUSIONS

Marvao Medical Devices, Ltd. believes the proposed NexSite HD Hemodialysis **Step Tip** Catheter for long term use is substantially equivalent to legally marketed predicate devices. The indications for use, methods of operation, design and materials used are either identical or substantially equivalent to existing legally marketed predicate products. In addition, performance testing supports substantial equivalence of the proposed and predicate devices.