February 8, 2018

Marvao Medical Devices, Ltd.
% Mary P. LeGraw
Principal Regulatory Consultant
Boston Biomedical Associates
100 Crowley Drive, Suite 216
Marlborough, MA 01752

Re: K173805
Trade/Device Name: NexSite™ HD, Hemodialysis Symmetric Tip Catheter for long term use
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MSD
Dated: December 18, 2017
Received: December 19, 2017

Dear Mary P. LeGraw:

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 tray 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173805

Device Name
NexSite™ HD, Hemodialysis Symmetric Tip Catheter for long term use

Indications for Use *(Describe)*
The NexSite™ HD, Hemodialysis Symmetric Tip Catheter for long term use is indicated for use in attaining long term vascular access for chronic hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include the subclavian vein which should only be used when no other upper extremity or chest wall options are available. 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.

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1 510(K) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date is December 11, 2017 [21 CFR 807.92(a)(1)].

1.1 Submitter

Name:	Marvao Medical Devices, Ltd.
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Contact Person:	Mary P. LeGraw, Boston Biomedical Associates 100 Crowley Drive Suite 216, Marlborough, MA 01752 mlegraw@boston-biomedical.com Phone: (508) 691-7038 Fax: (508) 351-8637

1.2 Device Name

Device/Trade Name:	NexSite™ HD, Hemodialysis **Symmetric Tip** Catheter for long term use
Date of Preparation:	December 14, 2017.
Common Name:	Catheter, hemodialysis, implanted
Classification Name:	Blood access devices and accessories
Classification Number:	876.5540
Product Code/ Classification Panel:	MSD/Gastroenterology /Urology

1.3 Predicate Device(s)

Primary	**K161026**	Marvao NexSite HD Hemodialysis Catheter for long term use, Manufactured by Marvao Medical Devices, Ltd.
Secondary	**K171571**	Marvao NexSite HD Hemodialysis Catheter for long term use (60cm),

		Manufactured by Marvao Medical Devices, Ltd.
Reference	**K123196**	Palindrome™ Precision Symmetric Tip Dual Lumen Catheter, Manufactured by Covidien

1.4 Device Description

The NexSite™ HD, Hemodialysis **Symmetric** Tip Catheter for long term use (19 cm, 23 cm, 37 cm, 31 cm, 35 cm and 55 cm (tip to cuff lengths) is a dual lumen, symmetric tip radiopaque polyurethane catheter which contains a Dacron biomaterial cuff and two female luer connectors. The DISC (Dermal Ingrowth Support Collar) assists with the direction of the catheter and consists of a biomaterial tissue ingrowth scaffold. The biomaterial scaffolds on the catheter shaft and DISC are aligned and facilitate tissue ingrowth, which is considered important in reducing the source of extraluminal infection in patients requiring long term catheterisation. The Catheter, DISC and the following ancillary components required for the procedure (0.038" guidewire, Stainless Steel Tunneler and Sleeve, 16Fr Introducer / Dilator and Luer Caps) are provided in a tray, sealed with a Tyvek lid and placed in a second sterile pouch so that the tray can be delivered to the sterile field.

1.5 Indications for Use

The NexSite™ HD, Hemodialysis **Symmetric** Tip Catheter for long term use is indicated for use in attaining long term vascular access for chronic hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include the subclavian vein which should only be used when no other upper extremity or chest wall options are available. Catheters greater than 40cm are indicated for femoral vein insertion.

1.6 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 NexSite™ HD **Symmetric Tip** devices and identified predicate devices was completed. The test results support the substantial equivalence of the NexSite™ HD **Symmetric Tip** device to the predicate devices.

1.7 Performance Data

In vitro testing was performed on the NexSite HD, Hemodialysis **Symmetric Tip** Catheter to assure reliable design and performance in accordance with ISO 10555-1:2013. The non-

clinical tests performed include visual and dimensional of the catheter, DISC and stylet, stylet joint strength, priming volume, catheter leakage, catheter pressure, catheter flow rate testing, catheter recirculation testing and mechanical hemolysis. The test results demonstrate that the NexSite™ HD, Hemodialysis **Symmetric 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.

1.8 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 *Guidance Industry and Food and Drug Administration Staff Implanted Blood Access Devices for Hemodialysis, January 21, 2016.*

1.9 Conclusions

Marvao Medical believes the proposed NexSite HD Hemodialysis **Symmetric 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.