March 24, 2022

Dib UltraNav Medical, LLC
% Noelle Sutton
Principal Consultant
The Tamarack Group - MPLS, LLC
2584 Upton Avenue South
Minneapolis, Minnesota 55405

Re: K213492
Trade/Device Name: Dib UltraNav Transseptal Catheter System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 18, 2022
Received: February 22, 2022

Dear Noelle Sutton:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel E. Neubrander -S

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213492

Device Name
Dib UltraNav Transseptal Catheter System

Indications for Use *(Describe)*
The Dib UltraNav Transseptal Catheter System is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal puncture.

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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510(k) Summary for The Dib UltraNav Transseptal Catheter System

Prepared March 24, 2022

Submitter

Manufacturer:	Contact Person:
Dib UltraNav Medical, LLC 123 W. Mills Avenue STE 600 El Paso TX 79901	Noelle Sutton Principle Regulatory Consultant The Tamarack Group – MPLS, LLC 763-670-6538 noelle.sutton@tgmpls.com

General Information

Device Name:	Dib UltraNav Transseptal Catheter System
Trade Name:	Dib UltraNav Transseptal Catheter System
Common / Usual Name:	Introducer Catheter
Classification Name:	Catheter Introducer
Product Code and Classification:	DYB; Class 2 – 21 CFR 870.1340
Review Panel:	Cardiovascular
Predicate Device:	VersaCross Transseptal Sheath (K183655)
Reference Device:	Swartz Braided Transseptal Guiding Introducer (K052644)

Intended Use / Indications for Use

The Dib UltraNav Transseptal Catheter System is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal puncture.

Device Description

The Dib UltraNav Transseptal Catheter System is a single-use, dual lumen, non-steerable intravascular catheter and handle to be used during a percutaneous procedure to support visualization and puncture of the septum. It is to be used to cross the interatrial septum and enable placement of a guidewire into the left side of the heart. The UltraNav catheter system is used with off-the-shelf transseptal needles and ultrasound catheters (not provided).

Substantial Equivalence

The Dib UltraNav Transseptal Catheter System, the predicate device and reference device are intravascular catheters designed to introduce various cardiovascular catheters or guidewires to all chambers of the heart, including the left atrium via transseptal puncture. The subject device, predicate device and reference device are similar in regulatory aspects, intended use, fundamental scientific

technology, including principles of operation and mechanism of action. The differences in design and technological characteristics between the subject device and the predicate device and reference device do not raise new questions of safety and effectiveness. The results of verification and validation testing provide reasonable assurance of substantial equivalence of the Dib UltraNav Transeptal Catheter System with the predicate device.

Safety and Performance Data

The Dib UltraNav Transseptal Catheter System was evaluated to demonstrate substantial equivalence. All test requirements were met. The Dib UltraNav Transseptal Catheter was subjected to the safety and performance tests described below.

Mechanical testing

To support substantial equivalence, bench testing evaluated critical visual, dimensional and mechanical performance characteristics of the Dib UltraNav Transseptal Catheter System. Testing was conducted in compliance with ISO 10555-1: 2013 Intravascular catheters – sterile and single-use catheters – Part 1: General requirements and Dib UltraNav Medical, LLC internal requirements. The following tests were performed:

- Freedom from leakage (air and liquid)
- Tensile strength
- Radiopacity
- Visual inspection
- Dimensional testing
- Luer connection testing
- Kink resistance/bend testing
- Torque testing
- Push transmittance
- Simulated use
- Handle performance related tests

Biocompatibility

The biological safety of the Dib UltraNav Transseptal Catheter System was evaluated in accordance with ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The following tests were performed:

- Cytotoxicity

- Acute Systemic Toxicity
- Irritation
- Pyrogenicity
- Sensitization
- ASTM Hemolysis
- Complement Activation
- Partial Thromboplastin Time
- Platelet and Leukocyte Count Assay
- *In Vivo* Thrombogenicity

Sterilization Validation

Sterilization validation was completed for the Dib UltraNav Transseptal Catheter System in accordance with the requirements of ISO 11135-1: Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. In accordance with the standard, the process is effective in providing a sterility assurance level (SAL) $\geq 10^{-6}$.

Packaging Validation

Packaging validation was performed to ensure that, after shipping and distribution simulation, the product and packaging maintain integrity. Package sterile barrier integrity and seal strength were tested in accordance with ISO 11607 Packaging for terminally sterilized medical devices (Parts 1 and 2).

Animal Testing

The *in vivo* safety and performance of the Dib UltraNav Transseptal Catheter System was evaluated in an acute GLP animal study using eight canines. The Dib UltraNav Transseptal Catheter System was used to deliver an ultrasound catheter, needle and guidewire into heart chambers and compared to the reference device. The study demonstrated safety, ability to facilitate an accurate puncture of the septum and ability to reliably deliver a guidewire to the left side of the heart.

To confirm that the UltraNav Transseptal Catheter System user interface has been designed such that errors that occur during normal use of the device that could cause harm or degrade medical treatment are eliminated or reduced to the extent possible, a usability assessment was performed by two independent users. The study demonstrated that the UltraNav could be used without operator use errors that lead to serious adverse events.

Conclusion

The intended use and fundamental scientific technology of the Dib UltraNav Transseptal Catheter System are similar to the predicate device, the VersaCross Transseptal Sheath (K183655) and reference

device, the Swartz Braided Transseptal Guiding Introducer (K052644). The results of safety and performance testing support the substantial equivalence of the Dib UltraNav Transseptal Catheter System to the predicate device. The differences in design and technological characteristics do not raise any new questions of safety and effectiveness.