November 14, 2022

VizaraMed, Inc.
Jack P Douglas, PhD
Vice President, Regulatory Affairs
1914 O'Toole Way
San Jose, California 95131

Re: K221655
Trade/Device Name: Multiflex Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 3, 2022
Received: June 7, 2022

Dear Dr. Jack Douglas:

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,

Ankurita Datta -S

Digitally signed by Ankurita Datta -S
Date: 2022.11.14 14:35:55 -05'00'

for 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)*
K221655

Device Name
Multiflex Steerable Sheath

Indications for Use *(Describe)*
The VizaraMed Multiflex Steerable Sheath is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

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

1. Date prepared	June 1, 2022
2. Manufacturer	VizaraMed, Inc.
3. Contact	Jack P Douglas, PhD Vice President, Regulatory Affairs VizaraMed, Inc. 1914 O'Toole Way San Jose, CA 95131 (510) 792-7477
4. Contract Manufacturer Name	Novel Cath (A Cirtec Company) 90 Great Oaks Blvd. San Jose, CA 95119
5. Device Identification	Trade Name: Multi*flex* Steerable Sheath Common Name: Introducer, Catheter Classification Name: Catheter Introducer Class: Class II, 21 CFR 870.1340 Product Code: DYB Classification Panel: Cardiovascular

6. Device Description

The VizaraMed Multi*flex* Steerable Sheath is a deflectable, sterile, single-use, percutaneous steerable sheath with dilator used to facilitate placement of various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

The sheath is available in two sizes and consists of a steerable shaft capable of three-dimensional shapes, a handle with lockable steering controls, a Tuohy-Borst adapter with a hemostasis valve, a side port, and atraumatic soft distal tip. The shaft is radiopaque for visualization under fluoroscopy. The accompanying dilator is packaged with the sheath in a pouch for removal.

The 12.5F sheath can accommodate devices of 3F(0.039”) - 12.5F (0.162”). The 15.5F sheath can accommodate devices sized 3F (0.039") - 15.5F (0.203”).

7. Intended Use

The VizaraMed Multi*flex* Steerable Sheath is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

8. Predicate Device
    - St. Jude Medical Agilis Steerable Introducer [K081645]
9. Reference Device
    - Cook, Inc. Extra Large Check-Flow Introducer [K203670]
10. Characteristics of Substantial Equivalence

The VizaraMed Multiflex Steerable Sheath is substantially equivalent to the predicate device based on the following:

- Indications for Use
- Specifications
- Product features
- Technological characteristics
- Product design
- Materials
- Sterilization method
- Mechanical testing
- Biocompatibility testing

The subject device was subjected to applicable testing to ensure reliable design and performance under testing parameters. The testing performed is described below:

11. Mechanical Properties

Mechanical testing, including dimensional verification, tensile testing, and leak testing, were conducted to ensure the Multi*flex* Steerable Sheath meets design requirements to support substantial equivalence to the predicate.

12. Sterilization and Packaging

Sterilization validation via ethylene oxide (EO) per ISO 11135 was conducted to ensure design requirements and to support substantial equivalence to the predicate. Sterilization validation used fractional and full cycles, and appropriate sample size of final pre-conditioned, packaged product that incorporated the use of biological indicators (BI) for the inoculated product (IP).

13. Usability Assessment

Subjective and objective evidence was obtained via questionnaire from physicians to assess critical tasks in a simulated heart model. Training was provided followed by user evaluation while manipulating the device.

14. Biocompatibility

The Vizaramed Sheath is considered to be a limited contact (≤24 hrs.), externally communicating device used in circulating blood. Testing was conducted for cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity and hemocompatibility. All tests were found to meet acceptance criteria, supporting substantial equivalence to the predicate.

15. Conclusions

The results of the tests support the conclusion that the VizaraMed Steerable Sheath meets design input requirements based on the intended use and that it is substantially equivalent to the predicate.