March 26, 2026

Vizaramed, Inc.
Jack Douglas, PhD
1914 O'Toole Way
San Jose, CA 95131

Re: K260626
Trade/Device Name: Multiflex Steerable Sheath (VIZ175)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 26, 2026
Received: February 26, 2026

Dear 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine N. Trivedi -S

Digitally signed by Katherine N. Trivedi -S
Date: 2026.03.26 21:28:29 -06'00'

Katherine Trivedi
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260626

Device Name
Multiflex Steerable Sheath 17.5F

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.

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

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510(k) SUMMARY

1. Date prepared	February 25, 2026
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. Device Identification	Trade Name: Multi*flex* Steerable Sheath 17.5F Regulation No: 21 CFR 870.1340 Regulation Name: Catheter Introducer Regulatory Class: Class II Product Code: DYB Classification Panel: Cardiovascular

5. 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 17.5F sheath is a steerable shaft capable of complex three-dimensional shapes, a handle with lockable steering controls, a Tuohy-Borst adapter with a hemostasis valve, a side port with 3-way stopcock, and atraumatic soft distal tip. The shaft is radio-opaque for easy visualization under fluoroscopy. The accompanying dilator is packaged with the sheath in a pouch for easy removal.

The 17.5F sheath can accommodate devices of 3F(0.039”) - 17.5F (0.230”).

6. 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.

7. Predicate Device

- 15.5F Vizaramed Steerable Introducer Sheath [K221655]

8. Reference Device

- Cook, Inc. Extra Large Check-Flow Introducer [K203670]

9. Characteristics of Substantial Equivalence

Substantial Equivalence (SE) was evaluated with the predicate device by review of available information for :

- Indications for Use
- Specifications
- Product features
- Technological characteristics
- Product design
- Materials
- Sterilization method
- Mechanical test results
- Biocompatibility test results
- Packaging and Labeling

These results have shown alignment in these above categories, save for details that are unavailable or proprietary, or where specifications or test results differ. These differences were not significant to impact overall SE determination since they do not impact risk evaluation.

10. Mechanical Properties

Numerous visual and mechanical test methods including tensile strength, kink resistance and deflection were employed to verify the Multi*flex* Steerable Sheath design could be used for its intended use and control potential risks as evaluated in the company Design Control Risk Management program. All test results met acceptance criteria.

11. Sterilization and Packaging

Sterilization validation employed an ethylene oxide (EO) method per ISO 11135 is the same as used by the predicate device.

12. Usability Assessment

The new size sheath has the same usability as the predicate device.

13. Biocompatibility

The Vizaramed Sheath is a limited contact (≤24 hrs.), externally communicating device used in circulating blood. Test results were obtained for the predicate device and similar 3-way stopcock for cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity and hemocompatibility. All tests were found to meet acceptance criteria, supporting the safety of biocompatibility.

14. Conclusions

Safety and efficacy testing for the 17.5F Multiflex Steerable Sheath met all company acceptance criteria across mechanical, dimensional, fluid flow, and functional test categories. The device's dimensional increase from the 15.5F predicate is modest and proportional, uses identical materials and construction, and does not alter the fundamental intended use, technological characteristics, or risk profile. The size increase is further contextualized by the FDA clearance of Class II catheter introducers up to 24.0F (K203670), demonstrating that larger bore devices in this product category have an established safety precedent. Biocompatibility is supported by prior testing on the predicate device and a comparable three-way stopcock, with no new materials introduced. Risk analysis under ISO 14971 confirmed no new hazards. Taken together, the analysis of product specifications, design features, materials, sterilization, performance testing, and indications for use—evaluated against the predicate 15.5F Multiflex Steerable Sheath (K221655)—demonstrates that the 17.5F Multiflex Steerable Sheath is substantially equivalent to the predicate and is appropriate for clearance under the Special 510(k) pathway.