September 18, 2019

Geomed Medizin-Technik GmbH & Co.
℅ Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Amstel 320-1
1017 AP Amsterdam
The Netherlands

Re: K183438
Trade/Device Name: Geomed Vascular Dilators
Regulation Number: 21 CFR 870.4475
Regulation Name: Surgical vessel dilator
Regulatory Class: Class II
Product Code: DWP
Dated: July 26, 2019
Received: July 30, 2019

Dear Angelika Scherp:

This letter corrects our substantially equivalent letter of September 3, 2019.

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,

Brian D. Pullin -S

Brian Pullin, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183438

Device Name
Geomed Vascular Dilators

Indications for Use *(Describe)*
Geomed Vascular Dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.

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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K183438

5. 510(k) SUMMARY

Date:	September 1, 2019	
Submitter:	Name:	Geomed Medizin-Technik GmbH & Co. KG
	Address:	Ludwigstaler Strasse 27 D-78532 Tuttlingen Germany
	Contact Person:	Hanno Haug
	Telephone:	+49.7461.93550
Product:	Name of Device:	Geomed Vascular Dilators
	Common Name:	Vascular Dilator
	Classification Name:	Surgical Vessel Dilator
	CFR Section:	870.4475
Predicate Device:	o K100518 – Instrumed Vessel Dilators This predicate has not been subject to a recall.	
Device Description:	Vascular Dilators are reusable stainless-steel surgical instruments that are used by qualified surgeons to enlarge or calibrate vessels. They are provided in two basic models and various sizes to accommodate individual needs, based on the anatomy of the site and the type of surgical procedure. The device is provided non-sterile for steam sterilization by the user.	
Indications for Use:	Geomed Vascular Dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.	
Technological Characteristics	The technological and performance characteristics of subject and predicate devices are identical, as shown by the following comparison table:	

Manufacturer	Geomed Medizin-Technik	Instrumed K100518
Indications for Use	Geomed Vascular Dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.	INSTRUMED vessel dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.
Design	Tapered tip connected to a handle by wire.	Tapered tip connected to handle by wire.
Garrett Vascular Dilator		
Tip Diameter	1.0-5.0 mm	1.0-5.0 mm
Length	140 mm / 210 mm	140 mm / 210 mm
DeBakey Vascular Dilator		
Tip Diameter	1.0-10.0 mm	1.0-10.0 mm
Length	190 mm	190 mm
Material	ASTM F 899-12b Stainless Steel	ASTM F 899-07 Stainless Steel
Patient Contact	Blood vessels, transient (<15 min.)	Blood vessels, transient (<15 min.)
Sterility	Non-sterile	Non-sterile
Reusable	Yes	Yes

Performance Testing: The subject Geomed Vascular Dilators are very similar to the predicate device in terms of intended use and technology. Design verification and validation testing to support determination of substantial equivalence consisted of the following tests:

- Tensile strength testing of the tip-to-wire and handle-to-wire bonds, indicating that the bond strength is sufficient to withstand forces experienced during clinical use
- Verification of device dimensions
- Validation testing of the recommended end user manual and automated cleaning procedures
- Validation testing of the recommended end user steam sterilization process
- Full-cycle validation testing of drying time after sterilization

Cleaning and sterilization validation testing was conducted in accordance with the recommendations outlined in FDA Guidance Document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (03/17/2015).

Acceptance criteria were met for all tests performed.

Conclusion: The subject device Geomed Vascular Dilators has the same technological characteristics and indications for use as the predicate device. The information provided in this 510(k) submission, including results of non-clinical testing, indicates that Geomed Vascular Dilators are substantially equivalent to the predicate device.