DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 29, 2017

Fetzer Medical Gmbh & Co. Kg
Mr. Harald Jung
Manager Quality/ Regulatory Affairs
Unter Buchsteig 5
D-78532 Tuttlingen
Germany

Re: K163524
Trade/Device Name: Fetzer Medical Vessel Dilator
Regulation Number: 21 CFR 870.4475
Regulation Name: Surgical Vessel Dilator
Regulatory Class: Class II
Product Code: DWP
Dated: May 30, 2017
Received: June 1, 2017

Dear Mr. Harald Jung:

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163524

Device Name
Vessel Dilators

Indications for Use *(Describe)*
Fetzer Medical vessel dilators are devices used to enlarge or calibrate a vessel during cardiovascular surgery.

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 K163524

1. Submitter Information

Submitter:	Fetzer Medical GmbH & Co. KG Unter Buchsteig 5 D-78532 Tuttlingen GERMANY
Contact Person:	Harald Jung, Manager Quality & Regulatory Phone: +49 7462 94799-182 Fax: +49 7462 94799-282
Date Prepared:	26.06.2017
Device Trade Name:	Fetzer Medical Vessel Dilators
Common / Usual Name:	Vessel Dilators
Classification Name	Dilator, Vessel, Surgical
Regulatory Class:	II
Product Code:	DWP
Regulation	21 CFR 870.4475 Surgical Vessel Dilator

2. Predicate Device:

	Primary Predicate	Secondary Predicate
Trade name	Instrumed Vessel Dilators	Geister Garrett, Cooley and Debakey Vessel Dilators
510(k) No.	K100518	K030788
510(k) submitter / holder	INSTRUMED INTERNATIONAL, INC. 626 Cooper Court Schaumburg, IL 60173, USA	Geister Medizintechnik GmbH Föhrenstr. 2 78532 Tuttlingen / Germany

3. Device Description:

Fetzer Medical Vessel Dilators are reusable manual surgical instruments. They are rod-like devices with a long, slender, solid shaft and a distal tip of various shapes and sizes.
They are sold unsterile and can be reused (cleaned and sterilized) according the instructions for use.

There are several types of dilators made from stainless steel or aluminum:

- Cooley Coronary Dilators
- Cooley Vessel Dilators
- Garrett Vascular Dilators
- Hiebert Vascular Dilators
- DeBakey Vascular Dilators
- Sarns-Style Dilators
- Myocardial Dilators

These dilators are available in a range of different length and diameters.

The handle of the DeBakey Vascular Dilator, the Cooley Vessel Dilator, the Cooley Coronary Dilator, the Hiebert Vascular Dilator and the Garrett Vascular Dilator is textured with one site flat. The handles of the Sarns and Myocardial Dilators are smooth. The Myocardial Dilator has a flat distal end for holding it and the Sarns Dilator has a hollow handle at the distal end.

Apart from the Hiebert Vascular Dilator and the Myocardial Dilator, the handle is connected to a thin shaft. The diameter of the shaft of the different dilator types varies. The shaft of the Cooley Coronary Dilator, the Cooley Vessel Dilator, The Garrett Vascular Dilator and the DeBakey Vascular Dilator can be thin so that the shaft is flexible. The handle of the Myocardial Dilator has no shaft while the Hiebert Vascular Dilator is double-ended; it possesses two flexible shafts, with the handle located in between the two thin shafts.

The tips of all dilators have the aim to enlarge a vessel. The design of the Sarns and Myocardial Dilator is similar to an elephant's tusk. The diameter increases steadily, moving towards the handle's direction. The tips of the other Dilators are olive-shaped. The Cooley Coronary Dilator possesses no formed tip. For all dilators, the penetrating diameter corresponds to the diameter of the shaft. The Hiebert Vascular Dilators working elements are each malleable wires with an olive tip in different diameters.

4. Comparison of Indications for Use

The Fetzer Medical Vessel Dilators have the same intended use as the predicate devices, although there are differences in the indications for use. The indications are further compared below:

	Subject Device	Primary Predicate	Secondary Predicate
Trade name	Fetzer Medical Vessel Dilators	Instrumed Vessel Dilators	Garrett, Cooley, and Debakey Vessel Dilator
Indication for use	Fetzer Medical vessel dilators are devices used to enlarge or calibrate a vessel during cardiovascular surgery.	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.	Geister 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.

5. Comparison of Device Design to predicate device

The subject and predicate devices are similar in terms of device design, with some additional geometries available in the subject device. The device designs are compared further below:

Fetzer Medical Vessel Dilators Device Configurations	Comparison to Predicate Devices
• Cooley Coronary Dilators • Cooley Vessel Dilators • Garrett Vascular Dilators • DeBakey Vascular Dilators	The Fetzer Medical Vessel Dilators were compared against the predicate devices in the following properties, and found to fall within the range offered under the predicate devices: • Tip geometry and dimensions • Handle and wire dimensions • Materials
• Hiebert Vascular Dilators	The predicate devices do not include Hiebert Vascular Dilator configurations. The Hiebert Vascular Dilators are the same as Garrett Vascular Dilator except they are double-ended.
• Sarns-Style Dilators • Myocardial Dilators	The Sarns-Style Dilators and Myocardial Dilators differ from the predicate devices in tip and handle geometry to accommodate larger vessels.

6. Comparison of Cleaning and Sterilization

The Cleaning and Sterilization for the Fetzer Medical Vessel Dilators are similar to the range conditions for the predicate devices:

	Subject Device	Primary Predicate	Secondary Predicate
Trade name	Fetzer Medical Vessel Dilators	Instrumed Vessel Dilators	Geister Garrett, Cooley, and Debakey Vessel Dilator
Cleaning	Instruments can be processed after disassembling in a combined manual pre cleaning and automated cleaning with a validated washer-disinfector prior to sterilization.	manual cleaning with soft sponge / soft brush no details in IFU	Instruments can be processed after disassembling in a combined manual pre cleaning and automated cleaning with a validated washer-disinfector prior to sterilization.
Sterilization	non-sterile Sterilization prior to use, using steam sterilization. **temperature:** 132 °C / 270 °F **exposure time:** 4 minutes **dry time:** 20 minutes	non-sterile to sterilize in steam Autoclav 270 °F, 15 min	non-sterile to sterilize with Prevacuum Steam Sterilization **temperature:** min 132 °C **exposure time:** minimum 3 min **dry time:** 30 min

7. Testing

The following performance data were provided in support of the substantial equivalence determination:

Test	Test Method Summary	Results
Automatic Reprocessing Validation according to ANSI/ AAMI ST81	Worst case devices were tested to verify that the instruments could be cleaned with the provided cleaning steps in the IFU. This test is performed by contamination of accessible, interior, and exterior surfaces of representative worst case instruments intending to reach the sites identified as the least accessible or most difficult to reach sites (worst case). According AAMI TIR 30, the effectiveness of the reprocessing cycle is evaluated by comparing visible contamination (red blood cells), residual protein, the number of organisms and the total organic carbon concentration recovered from the control instruments and the test instruments.	This validation provides evidence that contamination of the “Vessel Dilators” could be removed in health care facilities by the given cleaning and disinfection instructions.
Sterilization testing	The test is to verify that the devices could be sterilized with the provided sterilization procedure described in the IFU. The test specimens were contaminated with bio indicators or with a challenge suspension and were tested for sterility after the sterilization process. To assure a SAL of 10^-6 only a part cycle of the recommended sterilization process was performed in validation.	A reduction of test bacteria was observed and provided assurance that the device will be adequately sterilized under the validated sterilization parameters.
Biocompatibility testing	We conducted cytotoxicity testing according ISO 10993-5 for different materials and manufacturing lines.	All patient contacting materials were from the same material as the equivalent predicate devices. They were considered non cytotoxic for the indicated contact duration.

Test	Test Method Summary	Results
Mechanical tests	Pulling forces were applied to test the mechanical integrity of the devices.	All devices were able to withstand the required pulling force without deformation or failure.

The nonclinical testing demonstrated, that the Fetzer Medical Vessel Dilators are substantial equivalent to the predicate devices.

Performance Testing – Clinical / Animal

Clinical and animal testing were not conducted to support the substantial equivalence of this device to the predicates. The testing described above was adequate to address the differences between the subject device and predicate devices.

8. Substantial Equivalence

Substantial equivalence for the Fetzer Medical Vessel Dilators is based on similarities in intended use, design (function and operational principles), materials and labeling.

Although the indications for use are not identical between the subject device and the predicate devices, the intended use is the same.

Design and material of the different Fetzer Medical Vessel Dilators are within the range of those found in predicate devices except for the Myocardial Dilator and the Sarns-Style Dilators which are designed for larger vessels. Biocompatibility equivalence is supported by cytotoxicity testing conducted according to ISO 10993-5. The lager design of the Myocardial and the Sarns-Style Dilators does not raise new concerns regarding the substantial equivalence of the device to the predicate.

There are minor differences in the Cleaning and Sterilization compared to the predicate devices. Cleaning and Sterilization were verified with several performance tests.

Performance data demonstrate, that the Fetzer Medical Vessel Dilators comply with relevant standards and that they are substantially equivalent to the predicate devices.

9. Conclusion

Based on the comparison of the intended use, technological characteristics and performance testing, the subject device is substantially equivalent to the predicate.