DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 9, 2016

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

Re: K161004
Trade/Device Name: Fetzer Medical Self-Retaining Retractors
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor for Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: August 5, 2016
Received: August 8, 2016

Dear Mr. 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 yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K161004

Device Name
Fetzer Medical Self-Retaining Retractors

Indications for Use *(Describe)*

Fetzer Medical Self-Retaining Retractors are intended to hold the edges of a wound open during spinal 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

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:	2016-09-09
Device Trade Name:	Fetzer Medical Self-Retaining Retractors
Common / Usual Name:	Self-Retaining Retractors
Classification Name	Self-Retaining retractor for neurosurgery
Code of Federal Regulations (CFR)	21 CFR 882.4800
Regulatory Class:	II
Product Code:	GZT

2. Predicate Device:

Trade name	Instrumed Retractors	Versatrac™ Lumbar Retractor System
510(k) No.	K071771	K964402
510(k) submitter / holder	INSTRUMED INTERNATIONAL, INC. 626 Cooper Court Schaumburg, IL 60173	I V. Mueller Neuro/Spine 871 Industrial Rd. San Carlos, CA 94070, USA

3. Device Description:

Fetzer Medical Self-retaining Retractors are reusable manual instruments made from stainless steel, aluminum or titanium. They are sold unsterile and can be reprocessed (cleaned and sterilized) according the instructions for use.

Devices are available with the following features:

- frame type retractors consist of a toothed frame with one fixed shank and one moveable shank. The movable shank can be distracted via a pinion action with a wing screw or a turning knob to adjust it to the opening of the wound. It is self-retaining via a spring loaded ratchet lever and can be released by pressing this ratchet lever.
  Blades are exchangeable and available in different length and width configurations to adapt it to a wide range of patient anatomy.
  The shanks can be hinged to optimize the adjustment to the surgical site.

- Ring handle retractors consist of two conjoined shanks held via a spring loaded ratchet. Distraction is performed by pressing the ring handles together until the anatomical structures are distracted sufficiently.
  Ring handle retractors are available in different styles with fixed shanks and fixed blades. As well there are types with hinged shanks and exchangeable blades in different length and width configurations to adapt it to different patient anatomy.

- MIS Port retractor is a set of different modular tubular retractors of various length and diameter. They can be inserted over a dilator into the wound and is held by a table mounted adjustable flexible arm.

4. Indications for Use

Fetzer Medical Self-Retaining Retractors are intended to hold the edges of a wound open during spinal surgery.

5. Comparison of technological Characteristics to predicate device

	new device	predicate 1 Instrumed K071771	predicate 2 V. Mueller K964402
Trade name	Fetzer Medical Self-Retaining Retractors	Instrumed Retractors	Versatrac™ Lumbar Retractor System
Indications for use	Fetzer Medical Self-Retaining Retractors are intended to hold the edges of a wound open during spinal surgery.	INSTRUMED retractors are devices intended to provide minimally invasive access to the spine by ensuring the placement, positioning of the retractor down to the lamina, with its attachment to a flexible arm to provide a self-locking method of access to the spinal site through which tubes, microscopes and surgical instruments can be manipulated.	Spinal retractors are intended to hold the edges of a wound open during spinal surgery.
target population	For patients having a spinal surgery	not defined	same
Design frame type	**1 Frame type retractors:** The McCulloch type retractors consist of a titanium retractor frame with rigid or with hinged arms and several titanium blades (Muscle Blades / Hook Blades). M-Style Retractors consist of a stainless steel frame with hinged arms, extension bars and different colored aluminum blades. Blades are exchangeable and available in different length and width configurations to adapt it to a wide range of patient anatomy.	same as Instrumed Titanium Microdiscectomy System	same as SHADOW-LINE® McCULLOCH Lumbar Retractor
Design frame type and longitudinal with “snap in”	**2 Retractor systems with exchangable snap-in blades** These Systems consist of an expandable frame-type retractor with different exchangable snap-in blades. The shanks are hinged and the blades can be locked to the frame with a blade hub and auto-locking blade grasper. The transverse fram can be fixed to a table-mounted stainless steel retractor arm or a flexible titanium retractor arm to eliminate any retractor frame “drift”. As well there is a longitudinal ringhandle type retractor frame. It is available with the same hinged shanks and the same auto-locking blade grasper. The retractor frame can be black coated to reduce the glare. Blades are made from Aluminum or titanium in different length and width configurations.	same	same as SHADOW-LINE® Transverse Retractor same as SHADOW-LINE® Longitudinal Retractor
Design Distractor	**3 Vertebral Distractor** The vertical distractor is a frame type retractor consisting of a toothed frame with one fixed shank and one movable shank. The shank ends in a tube which can be pulled over a single use distraction screw.	same	same

	new device	predicate 1 Instrumed K071771	predicate 2 V. Mueller K964402
Design Spreader	**4 Vertebral Spreader** Vertebral spreaders consist of two conjoined shanks. The working end has a flat design with teeth or serrations at the outer side. The handle is formed with rings or with curved shank handles. It has a ratchet mechanism to hold the devices in any expanded position. As well there are frame type designs with toothed frame and pinion action mecha-nism. The devices are manufactured from stainless steel.	N/A	same
Design Scoville	**5 Scoville Hemilaminectomy Retractors** The Scoville Hemilaminectomy Retractors consist as well on a toothed frame with one fixed shank and one moveable shank. The shanks are hinged and the exchangeable retractor blades can be fixed to the shanks with a wing screw. Frame, shank and the different blades were made from stainless steel material.	N/A	same
Design Retractors with fixed blades	**6 Self-Retaining Ringhandle Retractors with fixed blades** There are several types of stainless steel self-retaining retractors with fixed blades. They consist of two conjoined shanks with permanent fixed blades / hooks. Some variations have curved or hinged shanks to maximize visibility of the operation site.	N/A	same
Design tubular retractors	**7 Tubular Retractor** This is a set of different modular tubular retractors of various length and diameter made from titanium. The tube can be positioned by an table mounted adjustable flexible arm or an rigid stainless steel arm. Available diameters: 14, 16, 18, 20, 22, 24, 26 mm Available length: 3 – 16 cm	same Diameter 14, 16, 18, 20, 22, 24, 26 mm Length: 3 – 16 cm	N/A
Materials	Stainless Steel (420, 304, 316) Aluminium AL6082T6 Titanium, B265 Grade 2/5	same	same
Biocompati-bility	External communicating device with limited contact to tissue / bone / dentin	same	same
Cleaning	Instruments can be processed in a combined manual pre cleaning and automated cleaning with a validated washer-disinfector prior to steri-lization.	manual cleaning with soft sponge / soft brush	similar shadow line, neuro retrac-tors, general instruments manual cleaning
Sterilization	non-sterile Sterilization prior to use, using steam steriliza-tion. 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 min 132 °C min 3 Min. exposure 30 min dry

6. Testing

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

Test	Test Method Summary	Results
Automatic Reprocessing Validation acc. ANSI/AAMI ST81	The test was performed to verify that the devices could be cleaned with the provided cleaning steps in the IFU. This test method 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 and the number of organisms recovered from the control instruments and the test instruments.	This validation provides evidence that viable microbiological contamination as well as a soil contamination of the “Self-retaining retractors” are removed 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 bioindicators 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 assured showing that contaminated test specimens are free of viable/augmentable bacteria after sterilization.
Biocompatibility testing	To verify the biocompatibility of all patient contacting materials, we evaluated them according ISO 10993-1. Fetzer Medical Self-Retaining Retractors were considered “tissue / bone contacting” devices with a contact duration of less than 24 hours. We performed several cytotoxic tests according ISO 10993-5 and sensitization / irritation tests according ISO 10993-10 for the different materials and manufacturing lines.	All tested devices were considered non cytotoxic and they did not cause any skin irritation reaction for the indicated contact duration.
Mechanical tests	Devices were tested for typical forces to hold a wound open during spinal surgery. Testing load was double to tribble the maximum load assumed during surgery.	All devices were able to withstand the required test load without deformation or failure.

The nonclinical testing demonstrated, that the Fetzer Medical self-retaining retractors are substantial equivalent to the predicate devices and perform as well as or better than the legally marketed predicate devices.

7. Substantial Equivalence

Substantial equivalence for the Fetzer self-retaining retractors is based on similarities in intended use, design (function, dimensions and operational principles), materials and labeling based on their promotional materials, labeling and clearance letter.

Slight differences in the intended use to the Instrumed device do not result in another indication or use at a different surgical site or with another patient population. Therefore the differences do not raise any new issues relating to the safety or effectiveness of the device.

Design and material of the frame type retractors (McCulloch / M-Style), the frame type and longitudinal retractors with “snap in”, the Vertebral Distractor, the Vertebral Spreader, the Scoville retractors and the ringhandle retractors with fixed blades is exactly same as the predicate devices from Instrumed and V.Mueller.

Design and material of the tubular retractors is same as predicate from Instrumed devices.

Minor differences in the Cleaning and Sterilization procedure result from a more detailed description for the Fetzer Medical self-retaining retractors. Cleaning and Sterilization is verified with several performance tests.

The minor differences between the Fetzer Medical self-retaining retractors and the predicate devices do not raise any new issues of safety or effectiveness.

Performance data demonstrate, that the Fetzer Medical self-retaining retractors do comply to relevant standards and that they are equivalent to the predicate devices.

8. Conclusion

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