DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 24, 2017

MEDICON eG
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K161680
Trade/Device Name: MEDICON Spinal Spreading Systems
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor for Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: February 21, 2017
Received: February 24, 2017

Dear Mr. Webb:

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,

Michael J. Hoffmann -S

for 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)*
K161680

Device Name
MEDICON Spinal Spreading Systems

Indications for Use *(Describe)*
The MEDICON Spinal Spreading Systems are used to spread soft tissue and maintain surgical access in spine surgery and may only be used by surgeons with proper training and adequate experience in spine 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.

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

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510(k) Summary

1. Submitter Information

Submitter:	Joachim Schmid MEDICON eG Gänsäcker 15 78532 Tuttlingen GERMANY (49) 7462 2009-0 Tele email: sales@medicon.de
Contact Person:	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Date Prepared:	February 17, 2017
Device Trade Name:	Medicon Spinal Spreading Systems
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:	Fetzer Medical Self-Retaining Retractors	Versatrac™ Lumbar Retractor System	Cervical Self-Retaining Retractor
510(k) No.:	K161004	K964402	K935529
510(k) submitter:	Fetzer Medical GmbH & Co. KG	I V. Mueller	Koros Surgical Instruments, Corp

3. Device Description:

Device Description:

The MEDICON Spinal Spreading System is made up of multiple reusable manual spreader systems. The spreaders include components for all approaches in spine surgery, including those specifically for cervical spine surgery, as well as inter-laminar, trans-laminar, extra-foraminal and dorsolateral approaches. The multiple components support classic and minimally invasive procedures. The components are made from a radiolucent x-ray compatible material, from titanium, some from stainless steel, and some from anodized aluminum.

The spreader models (accessories) include:

Spreader	**Accessories**
Spread-iT Retractor Set I & Set II	titanium hooks, blades & depth gauge
retraCT system set	PEEK blades, wrench & screwdriver
Cervicalino System	Bay blades, handle
Piccolino counter retractor	spreading sleeves, trocar sleeves, dilator set & handles
Caspar laminectomy spreader	blades & hooks
Hauser French retractor	blades & speculums

	Spinal retractor	blades
	Scoville laminectomy retractor	blades
	Haverfield Scoville lamin retractor	blades & handle
	Haverfield Scoville	
	Inge lamina spreader	hooks & blades
	Williams retractor	
	Cervical tissue retractor	
	Cloward lamina spreader	
	Cloward cervical spreader	
	Markham Meyerding retractor	

4. Indications for Use

The MEDICON Spinal Spreading Systems are used to spread soft tissue and maintain surgical access in spine surgery and may only be used by surgeons with proper training and adequate experience in spine surgery.

5. Comparison of technological Characteristics to predicate device

	New Device	**Predicate 1 - Fetzer Medical (K161004)**	**Predicate 2 - V. Mueller (K964402)**	**Predicate 3 - T. Koros (K935529)**
Trade name:	Medicon Spinal Spreading Systems	Fetzer Medical Self-Retaining Retractors	Versatrac™ Lumbar Retractor System	Cervical Self-Retaining Retractor
Indications for use:	The MEDICON Spinal Spreading Systems are used to spread soft tissue and maintain surgical access in spine surgery and may only be used by surgeons with proper training and adequate experience in spine surgery.	Fetzer Medical Self-Retaining Retractors are intended to hold the edges of a wound open during spinal surgery.	Same	Same
Design				
Expandable Frame type retractors:	The expandable frame type retractors consist of an expandable toothed rack, two rigid or hinges blade support arm, blade supports and different blade styles and types blades can be attached. Blades are exchangeable and can be snap-loaded from the side or from the top or slide on the arm	Same	Same	Same
Expandable Ring handle type retractors:	The expandable ringhandle type retractors consist of two ring handles, a catch, a joint. two shanks and fixed or exchangeable blades/hooks. The exchangeable blades can be snap-loaded from the side or from the top.	Same	Same	Same

Vertebral Spreaders:	Vertebral spreaders consist of two conjoined shanks and have a catch. The working end has a flat design with teeth or serrations at the outer side. These spreaders have ring-handles or shank handles.	Same	Same	N/A
Tubular Retractor:	Tube retractors are used for minimal invasive access and are available in various lengths and diameters. The tube can be fixed to a holding arm or held with manual handles.	Same	Same	N/A
Materials:	Stainless steel (ASTM F899)	Same	Same	Same
	Titanium alloy, Ti-6Al-4V (ASTM F136)	Same	Same	Same
	CP titanium (ASTM F67)	Same	Same	Same
	Aluminum 6082 (EN 473-3)	Same	Same	Same
	PEEK CA/CF 30	N/A	N/A	N/A
	Polyphenylsulfone (ASTM D6394) ***(only for accessories)***	N/A	N/A	N/A
	Polypropylene (ASTM D4101) ***(only for accessories)***	N/A	N/A	N/A
	Silicone ***(only for accessories)***	N/A	N/A	N/A

6. Testing

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

	Test Method Summary	**Results**
Non-clinical Test Summary:	Biocompatibility testing	Acceptable results
	Cleaning validation of worst case components (AAMI TIR30:2011)	No visible soil was seen on the test articles.
	Steam Sterilization Validation of worst case components (ISO 17665-1: 2006)	Each component met the acceptance criteria.
	Test to determine the strength of blade supports	Blade supports met acceptance criteria
	Test to determine the strength of blades	Blades met acceptance criteria
	Engineering analysis to determine strength testing worst case	Worst case was determined
Clinical Test Summary:	No clinical studies were performed	
Conclusions: Non-clinical and Clinical:	Medicon considers the Spinal Spreading Systems to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use	

7. Substantial Equivalence

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

8. Conclusion

The minor differences between the Medicon Spinal Spreading Systems and the predicate devices do not raise any new issues of safety and effectiveness. Non-clinical testing demonstrates that the Medicon Spinal Spreading Systems do comply to relevant standards and they are equivalent to the predicate devices. Based on the comparison of technological characteristics and non-clinical testing the subject device is substantially equivalent to the predicate.