August 29, 2018

Geister Medizintechnik GmbH
Christian Grotzinger
Quality Manager
Forhenstrasse 2
Tuttlingen, 78532 De

Re: K180610
Trade/Device Name: Geister retractor for neuro - and spine surgery
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor For Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: July 2, 2018
Received: July 9, 2018

Dear Christian Grotzinger:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180610

Device Name
Geister® Retractor for neuro- and spine surgery

Indications for Use *(Describe)*
The device intended for use as a specialized manual surgical instrument. It is reusable and intended to provide access to the thoracic and lumbar spinal column during minimally invasive and endoscopic surgical procedures. Provides a selflocking type surgical retraction system with inflatable tissue protectors.

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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K180610

VOLUME 006

510(k) Summary

DATE OF APPLICATION: 2018-08-28

APPLICANT: Geister Medizintechnik GmbH
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1. Device Name

1.1. Retractor

Trade Names: Geister® retractor for neuro – and spine surgery
Regulation description: Self-retaining retractor for neurosurgery

2. Classification Product Code / Subsequent Code

2.1. Retractor

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Retractor, Self-retaining, For Neuro-surgery	Part 882	Neurology	GZT	2	882.4800

3. Predicate Device

Geister Retractor are equivalent to the following predicate devices, most recently cleared by the FDA:

Geister Product	**Primary Predicate Device**	**510(k) Number**	**510(k) Holder**
Geister® retractor for neuro – and spine suregery	miaspas® miniTTA	K003740	Aesculap
	Predicate Devices	**510(k) Number**	**510(k) Holder**
	Versatrac™ lumbar retractor system	K964402	V.Müller
	Grossman self-retaining low profile brain retractor	K060097	KLS Martin
	Codman lhalo split ring retractor system	K913233	Codman

4. Description of the Device

4.1. Self-retaining retractor for neurosurgery

Dimensions retractor	65mm to 542mm
Dimensions blades	10mm to 180mm
Materials	Titanium (3.7165 - TiAl6 V4), Stainless Steel (1.4021 - X20Cr13 & 1.4305 - X12CrNiS18-8) & PEEK black
Coatings	Black coated, blue & green anodized
Retractor system / groups	Microdiscectomy Retractors, SpineControl Cervical Retractor System & Self-Retaining Retractors

5. Indications for Use

The device intended for use as a specialized manual surgical instrument. It is reusable and intended to provide access to the thoracic and lumbar spinal column during minimally invasive and endoscopic surgical procedures. Provides a self-locking type surgical retraction system.

6. Device description

GEISTER Medizintechnik GmbH Self-retaining Retractors are reusable manual instruments made from stainless steel, PEEK or titanium. They are sold unsterile and can be re-processed according the instructions for use.

6.1. Microdiscectomy Retractors

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.

6.2. SpineControl Cervical Retractor System

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.

6.3. Self-Retaining Retractors

Frame type & ring handle retractors. 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.

7. Testing

The following testing done to show safety and effectiveness of our system:

- Biocompatibility
- Re-processing and sterilization
- Performance testing bench

8. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, GEISTER's retractor for neuro – and spine surgery is considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications. There are no differences between the devices which would raise new issues of safety or effectiveness.