June 6, 2025

Geister Medizin Technik GmbH
Florian Herb
QM/RA Manager
Foehrenstrasse 2
Tuttlingen, Baden 78532
Germany

Re: K242759
Trade/Device Name: Geister K-Rex rongeurs
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: May 6, 2025
Received: May 6, 2025

Dear Florian Herb:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2025.06.06 14:56:19 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242759

Device Name

Geister® K-Rex™ rongeurs

Indications for Use *(Describe)*

The GEISTER® K-Rex™ rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

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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K242759

510(k) Summary

DATE OF APPLICATION: June 5, 2025

APPLICANT: Geister Medizintechnik GmbH
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CONTACT PERSON: Florian Herb
Quality Manager

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1. Device Name

Trade Names: Geister® K-Rex™ rongeurs
Regulation description: Manual rongeur

2. Classification Product Code / Subsequent Code

2.1. Rongeur

Device	Review Panel	Product Code	Device Class	Regulation Number
Rongeur, Manual	Neurology	HAE	2	882.4840

3. Predicate Device

Geister Rongeur are equivalent to the following predicate devices:

Geister Product	Predicate Device	510(k) Number	510(k) Holder
Geister® K-Rex™ rongeurs (new device)	CERAMO® KERRISION (primary predicate)	K153243	Fehling instruments
	SQ.line KERRISON	K223596	Aesculap Inc.

4. Description of the Device

Geister Geister® K-Rex™ rongeurs are reusable stainless steel instruments that are coated with TiAIN that are sterilizable and packaged non-sterile.

4.1. Device specifications

Bite Size:	1 – 6 mm
Length:	180 – 280 mm
Jaw opening	12 mm
cutting angles	40° and 90° up
Footplates	regular footplates and thin footplates
Materials	The products are made of stainless steel according to ISO 7153-1 and ASTM F899
Coatings	TiAIN
Further characteristics	Detachable, with Ejector

5. Indications for Use

The GEISTER® K-Rex™ rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

6. Substantial Equivalence Discussion

#	NEW DEVICE	PRIMARY PREDICATE DEVICE	PREDICATE DEVICE
510(k) Submitter/ Holder	Geister Medizintechnik GmbH	Fehling instruments	Aesculap, Inc.
Trade Name	K-Rex™ Rongeur	CERAMO® KERRISION	SQ.line KERRISONS
Illustration			
Device	Rongeur, Manual	Rongeur, Manual	Rongeur, Manual
Regulation Number	882.4840	882.4840	882.4840
Device Class	II	II	II
Classification Product Code	HAE	HAE	HAE
510(k) Number	new	K153243	K223596
Indications for use	The GEISTER® K-rex™ rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.	Fehling rongeurs (bone punches) are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.	The SQ.line KERRISONS (bone punches) are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.
Sterility	Non-sterile condition	Non-sterile condition	Non-sterile condition
Prescription Use	Yes	Yes	Yes
Material	Stainless steel 420, 303, and 301 (ASTM F-899); Surface coatings: black coating (TiAlN)	420 and 304 Stainless Steels (ASTM F-899); Surface coatings: CERAMO® (TiAlN);	Stainless Steels (ASTM F-899); Surface coatings: DLC black coating
Shaft lengths	180 – 280 mm	110 – 400 mm	180 – 280 mm
Jaw sizes	1 – 6mm	0.8-8 mm	1 – 6mm
Jaw angles	40° and 90° up cutting angles	Straight and 40 – 90° (up & down)	90 – 130° (up & down)
Jaw opening	12 mm	9 – 19 mm	10 – 15 mm
Ejector	Yes	Yes	Yes
detachable	Yes	Yes	Yes
Profile footplates	Regular and thin	Regular and thin	Regular and thin

Geister K-Rex™ Rongeurs have the same intended use, similar performance characteristics, are manufactured from similar materials and are similar in design to the predicate devices.

7. Non-Clinical Performance Data

Biocompatibility:

Biocompatibility end points were evaluated in accordance with ISO 10993. Biocompatibility testing for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, interactions with blood, hemolysis and material mediated pyrogenicity were performed. Test results indicate that the GEISTER® K-rex™ rongeurs are biocompatible.

Reprocessing, Cleaning and Sterilization:

Reprocessing, Cleaning and Sterilization validation were performed according to ANSI/AAMI ST98:2022, ISO 17665 and ISO 17664.

Cutting performance test:

A cutting performance test was performed on the GEISTER® K-rex™ rongeur and the predicate device. A cutting test of 10,000 cycles was performed. Compared to the predicate device, the GEISTER® K-rex™ rongeur demonstrates a similar cutting performance.

8. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device.

9. Substantial Equivalence Summary / Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in these 510(k) submissions that the difference between the Geister K-Rex™ Rongeurs and the predicate devices do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the Geister K-Rex™ Rongeurs are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use. Geister K-Rex™ Rongeurs are determined to be substantially equivalent to the referenced predicate devices.