March 3, 2023

Morpheus AG
Dimitri Krutsch
QM / RA Manager
Bahnhofstraße 18
Spaichingen, Baden Würrtemberg 78549
Germany

Re: K230256
Trade/Device Name: Rebellion, Phantom Multi-Bite Kerrison Rongeur
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: January 30, 2023
Received: January 31, 2023

Dear Dimitri Krutsch:

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/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 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 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: 2023.03.03 09:08:29 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230256

Device Name
Rebellion, Phantom Multi-Bite Kerrison Rongeur

Indications for Use *(Describe)*
The Rebellion is intended for cutting and removing bone, vertebral bodies and tissue in orthopedics, neurosurgery and spine 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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DATE OF APPLICATION: 01/30/2023
510(k) Number: K230256

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1 Device Name

Trade Name:	*Rebellion;* *Phantom Multi-Bite Kerrison Rongeur*
Common Name:	*Kerrison Rongeur*
Device Classification Name:	*Manual rongeur*

2 Classification / Product Code

Rebellion can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Product Code	Regulation Number	Device Classification
Rebellion	Manual rongeur	Neurology	HAE	21 CFR 882.4840	II

3 Predicate Device / Reference Device

Subject Device	Predicate Device	Reference Device	510(k) number	510(k) Holder
Rebellion	Rebellion; Phantom Multi-Bite Kerrison Rongeur	—	K200768 K221818	Morpheus AG

4 Device Description

The REBELLION is a Bone Punch and it is available in the length 250 mm, 200 mm and 160 mm with tree different tip sizes (2, 3 and 3 mm). At posterior tube the Rebellion can be connected to the Morpheus Bone and Tissue Trap or to a standard suction system via sterile tubing.

Figure 1: Rebellion

5 Indications For Use

The REBELLION is intended for cutting and removing bone, vertebral bodies and tissue in orthopedics, neurosurgery and spine surgery involving the skull or spinal column.

6 Technological Characteristics

Morpheus Rebellion possesses similar technological characteristics as compared to the predicate device K200768 and K221818. Different characteristics do not raise different questions of safety and effectiveness, and scientific methods were applied to evaluate different characteristics' effects on safety and effectiveness.

6.1 Device Characteristics Table

Description	Subject Device	Predicate Device Morpheus AG (Rebellion)
510(k)	K230256	K200768 K221818
Product Code	HAE	HAE
Class	II	II
Regulation #	882.4840	882.4840
Classification Name	Manual, Rongeur	Manual, Rongeur
Indication for Use	Identical	The Rebellion is intended for cutting and removing bone, vertebral bodies and tissue in orthopedics, neurosurgery and spine surgery involving the skull or spinal column.
Anatomical location	Skull and spine	Skull and spine
Sterility	Sterile	Sterile
Re-Use	No	No
Material	Stainless Steel: 420, 304 and 302 Polymer: PVC, ABS, PA6 GF60 (Grivory GV-6H); TPE (TM5MED) and Fluoropolymer (Altera MT1000A)	Stainless Steel: 420, 304 and 302 Polymer: PVC, ABS, PA6 GF60 (Grivory GV-6H); TPE (TM5MED) and Fluoropolymer (Altera MT1000A)
Patient Contacting	Stainless Steel: 420, 304 Polymer: Fluoropolymer (Altera MT1000A)	Stainless Steel: 420, 304 Polymer: Fluoropolymer (Altera MT1000A)
Design features	Manual Rongeur	Manual Rongeur
Bone Removal	Suctional function	Suctional function
Shaft-length	160, 200 and 250 mm	160, 200 and 250 mm
Jaw opening	14 mm	14 mm
Bite size	2 – 4 mm	2 – 4 mm
Cutting angulation	90° up-biting	90° up-biting
Packaging (sterile barrier system)	double packed in a PET/PP composite film	double packed in a PET/PP composite film
Shelf life (packaging)	5 years	2 years

7 Performance Data

7.1 Clinical performance testing

Clinical performance testing was not submitted in this 510(k).

7.2 Non-Clinical performance testing

The subject device does not represent a new worst-case when compared to the previously cleared Morpheus REBELLION Rongeur (K200768 and K221818).

To verify the shelf life of the sterile barrier system (SBS), a shelf-life validation according to ISO 11607-1 was performed for 5 years.

8 Conclusion

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Morpheus AG concludes that the Rebellion Rongeur is as safe and as effective for their intended use as the predicate devices, the Rebellion Rongeur (K200768 and K221818).