May 4, 2021

Morpheus AG
Timo Rack
CEO
Bahnhofstrasse 20
Spaichingen, 78549 DE

Re: K200768
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: March 29, 2021
Received: April 2, 2021

Dear Timo Rack:

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, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200768

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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Morpheus AG
Rebellion
510(k) Premarket Notification

DATE: 05/04/2021

510(k) Number: K200768

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Morpheus AG
Rebellion
510(k) Premarket Notification

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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	Fehling Punches	--	K153243	Fehling Instruments GmbH & Co. KG
	--	Steribite	K180949	RJR Surgical, Inc.

4 Device Description

The Rebellion is a Bone Punch and it is available in two lengths (200 – 250 mm) with tree different tip sizes (2, 3 and 3 mm). The Rebellion can be connected to a rinsing solution (NaCl 0,9%) via integrated Luer Lock connection. The tubes are flushed with the rinsing solution, so a clogging of the tube is prevented. At posterior tube the Rebellion can be connected to the Morpheus Bone and Tissue Trap or to a standard suction system via sterile tubing.

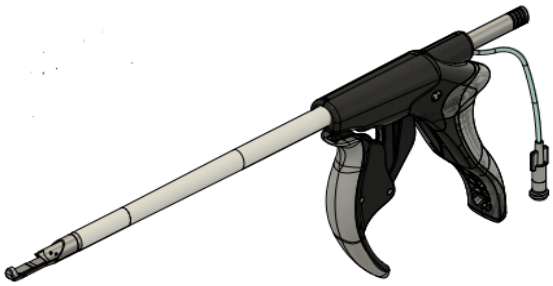

Figure 1: Rebellion

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 K153243 and reference device K180949.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 Fehling Instruments GmbH & Co. KG (Fehling-punches)	Reference Device RJR Surgical, Inc. (Steribite)
510(k)	--	K153243	K180949
Product Code	HAE	HAE	HAE
Class	II	II	II
Regulation #	882.4840	882.4840	882.4840
Classification Name	Manual, Rongeur	Manual, Rongeur	Manual, Rongeur
Indication for Use	The Rebellion is indicated to cut and remove bone, vertebral body and tissue in the orthopedic, neuro and spine 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 Steribite® Rongeur is a manually operated instrument indicated for cutting or biting bone during surgery involving the skull or spinal column.
Anatomical location	Skull and spine	Skull and spine	Skull and spine
Sterility	Sterile	Non-Sterile	Sterile
Re-Use	No	Yes	No
Material	Stainless Steel: 420, 304 and 302 Polymer: PVC, ABS, PA6 GF60 (Grivory GV-6H); TPE (TM5MED) and Fluoropolymer (Altera MT1000A)	420 and 304 Stainless Steels; Coating: CERAMO® (TiAlN) Polymer: Silicone	420, 17- 4PH, 302 and 316 stainless steel; Polymer: polyarylamide resin
Patient Contacting	Stainless Steel: 420, 304 Polymer: Fluoropolymer (Altera MT1000A)	420 and 304 Stainless Steels; CERAMO® (TiAlN)	420 and 17- 4PH stainless steel
Design features	Manual Rongeur	Manual Rongeur	Manual Rongeur
Bone Removal	Suction	Manual	Manual
Shaft-length	200 – 250 mm	110 – 400 mm	200 – 280 mm
Jaw opening	14 mm	9 – 19 mm	Not known
Bite size	2 – 4 mm	0.8 – 8 mm	1 – 5 mm
Cutting angulation	90° up-biting	40° and 90° up/down biting	40° up-biting

7 Performance Data

7.1 Clinical performance testing

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

7.2 Biocompatibility

The Morpheus Rebellion is categorized as an external communicating device with limited contact (≤24 h) with tissue/bone. The appropriate biocompatibility endpoints that were assessed include:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systematic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

7.3 Sterilization

Sterilization validation was conducted in accordance with ISO 11135:2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.

7.4 Packaging and Shelf Life

Packaging and Shelf Life validation was conducted in accordance with ISO 11607:2017, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.

7.5 Functional performance data

To verify function and performance under simulated environmental and application conditions, a cadaver test was performed in an operating room with two potential users.

A product validation was also performed in which the product was tested up to the maximum life cycle by cutting simulated bone.

8 Conclusion

Morpheus Rebellion possesses indications for use and technological characteristics similar to the predicate devices. The performance testing demonstrated that the device is as safe and effective as the predicate and has equivalent performance to the predicate. Therefore, Morpheus Rebellion is substantially equivalent to the predicate.