June 3, 2021

Zethon Ltd
Faith Green
Quality and Regulatory Engineer
2 Halton Brook Business Park
Aylesbury, Buckinghamshire HP22 5WF
United Kingdom

Re: K193630
Trade/Device Name: hekaDrill
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: Class II
Product Code: HBC, HBB, HBE, HSZ, GEY

Dear Faith Green:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 9, 2021. Specifically, FDA is updating this SE Letter to remove the ERL product code, since the device was not reviewed for ENT indications, as an administrative correction. Also, the GEY product code was added.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Adam Pierce, OHT5: Office of Neurological and Physical Medicine Devices, adam.pierce@fda.hhs.gov, (240) 402-6128.

Sincerely,

Adam D. Pierce -S
2021.06.03 11:40:47 -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

April 9, 2021

Zethon Ltd
Faith Green
Quality and Regulatory Engineer
2 Halton Brook Business Park
Aylesbury, HP22 5WF United Kingdom

Re: K193630
Trade/Device Name: hekaDrill System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBC, HBB, HBE, HSZ, ERL
Dated: March 9, 2021
Received: March 12, 2021

Dear Faith Green:

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
2021.04.09 15:22:46 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193630

Device Name
hekaDrill System

Indications for Use *(Describe)*
The hekaDrill system is intended for use in surgical procedures involving incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone. The system is specifically intended for use in neurologic and general surgical procedures.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

10 March, 2021

I. Company: Zethon Ltd
2 Halton Brook Business Park
Weston Road
Aston Clinton
Buckinghamshire
HP22 5WF
United Kingdom

Contact: Faith Green
Quality and Regulatory Engineer
Telephone Number: (+44) 01296634090
Email: faith.green@zethon.com

II. Proprietary Trade Name: hekaDrill

III. Common Name: High Speed System

IV. Classification Name: Motor, Drill, Electric (21 CFR 882.4360)
Motor, Drill, Pneumatic (21 CFR 882.4370)
Motor, Surgical Instrument, AC-Powered (21 CFR 878.4820)
Drills, Burs, Trephines & Accessories (21 CFR 882.4310)

V. Classification: Class II

VI. Product Code: HBC, HBB, HBE, HSZ, GEY

VII. Product Description:

The hekaDrill System consists of electric and pneumatic drill handpieces, a power console, footswitches, attachments, connection cables, irrigation tube kits, cutting tools, and system accessories. The handpieces, attachments, and system accessories are provided non-sterile and are reusable. The console and footswitches are reusable and are not intended to be sterilised. The cutting tools and irrigation tube kits are provided sterile and are single use.

VIII. Indications for Use:

The hekaDrill system is intended for use in surgical procedures involving incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone. The system is specifically intended for use in Neurologic and general surgical procedures.

IX. Identification of Legally Marketed Devices (Predicate Devices)

- Midas Rex Legend EHS Electric Drill System (K081475)
- Midas Rex MR8 Drill System (K163565)
- Midas Rex MR7 Pneumatic High Speed System (K090112)
- Midas Rex Legend System (K020069)

X. Comparison of the Technological Characteristics

The Midas Rex Drill Systems that are currently available on the market consist of both pneumatic and electric handpieces, consoles, footpedals, attachments, cutting tools and system accessories. The predicate device is similar to the system under review in that air or electric energy is used to supply power to the handpiece which then operates interchangeable cutting tools that are supported by interchangeable attachments. Both systems have the same indications for use and both use similar materials. A full comparison of the two devices demonstrated that any of the differences between the devices do not have an impact on safety and effectiveness or its ability to perform its intended use.

XI. Discussion of the Performance Testing

The following testing has been performed on the hekaDrill system in order to demonstrate the functionality of the device. A summary of this testing is as follows:

Test performed	Description of testing	Conclusion
General Performance		
Performance Validation	Cutting performance was compared to predicate drill system in terms of vibration, noise, control and performance.	Cutting performance was equivalent or better to that of predicate device
Electrical Performance		
Electrical Safety	Electric powered instruments evaluated for electrical safety	Instruments conform to IEC 60601-1:2005 for electrical safety.
Electromagnetic Compatibility	Electric powered instruments evaluated for electromagnetic compatibility	Instruments conform to IEC 60601-1-2:2014 for electromagnetic compatibility.
Biocompatibility		
Cytotoxicity – L929 MEM Elution	There was no biological reactivity (Grade 0) of the cells exposed to the test article extract.	Non-cytotoxic
Sensitization – Kligman Maximization	The extracts of the test article, elicited no reaction at the challenge (0% sensitization)	Non-sensitizer
Irritation – Intracutaneous Injection	The test article sites did not show a significantly greater biological reaction than the control article.	Non-irritant
Systemic Toxicity	The test article did not induce a significantly greater biological reaction than the control extracts.	Non-toxic
Pyrogenicity	The test article did not induce a Pyrogenic response.	Non-pyrogenic
Indirect Hemolysis	The test article led to a hemolysis index above the negative control of 0.14%.	Non-hemolytic

XII. Conclusions

The hekaDrill system is substantially equivalent to the predicate devices, as shown through comparisons and testing.