March 14, 2024

Zethon Ltd
Faith Robertson
Senior Quality and Regulatory Officer
2 Halton Brook Business Park
Aston Clinton, Buckinghamshire HP22 5WF
United Kingdom

Re: K233958
Trade/Device Name: hekaDrill
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, And Throat Electric Or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL, HBC, HBB, HBE, HSZ, GEY
Dated: November 8, 2023
Received: December 15, 2023

Dear Faith Robertson:

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.

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K233958

Device Name

hekaDrill

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, bone and biomaterials. The system is specifically intended for use in Neurosurgical (Cranial including craniotomy); Ear, Nose and Throat (ENT), Maxillofacial, Orthopedic, Arthroscopic, Spinal, Stemotomy, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

22nd February 2024

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

Contact: Faith Robertson
Senior Quality and Regulatory Officer
Telephone Number: (+44) 01296634090
Email: faith.robertson@zethon.com

II. Proprietary Trade Name: hekaDrill

III. Common Name: High Speed System

IV. Classification Name: Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece (21 CFR 874.4250)
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: ERL, 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, bone and biomaterials. The system is specifically intended for use in Neurosurgical (Cranial including craniotomy); Ear, Nose and Throat (ENT), Maxillofacial, Orthopedic, Arthroscopic, Spinal, Sternotomy, and General Surgical Procedures.

IX. Identification of Legally Marketed Devices (Primary Predicate Device)
- Skeeter Ultra-Lite Oto-Tool Drill (Accessory of K041523)

X. Identification of Legally Marketed Devices (Secondary Predicate Devices)
- Midas Rex MR8 Drill System (K163565)
- Midas Rex Legend EHS Electric Drill System (K081475)
- Midas Rex MR7 Pneumatic High Speed System (K090112)

XI. Comparison of the Technological Characteristics

The primary predicate (Skeeter Ultra-Lite Oto-Tool Drill system) consists of a dedicated electric handpiece, consoles, footpedals and a range of cutting accessories. The primary predicate device is similar to the system under review in that electric energy is used to supply power to the handpiece which then operates interchangeable cutting tools. Both systems have ENT specific indications for use.

In addition, the secondary predicate devices (Midas Rex Drill Systems) are currently available on the market consisting of both pneumatic and electric handpieces, consoles, footpedals, attachments, cutting tools and system accessories. The secondary predicate devices are 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.

In summary, a full comparison between the predicate devices and the hekaDrill system 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.

XII. 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

XIII. Conclusions

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