May 4, 2023

Hubly Inc.
Julie Byars
Quality Lead
750 Warrenville Rd, Suite 303
Lisle, Illinois 60532

Re: K230619
Trade/Device Name: Hubly Electric Drill (H100)
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBE
Dated: March 1, 2023
Received: March 6, 2023

Dear Julie Byars:

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: 2023.05.04 08:55:18 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K230619

Device Name
Hubly Electric Drill

Indications for Use *(Describe)*
The Hubly Electric Drill is a single-use, sterile, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.

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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A. Device Information:

Category	Comments
Sponsor:	Hubly, Inc. Casey Grage 750 Warrenville Rd. Suite 303 Lisle, IL 60532 (844) 482-5942
Correspondent Contact Information:	Julie Byars 750 Warrenville Rd. Suite 303 Lisle, IL 60532 901-848-4010
Device Common Name:	Powered Cranial Drill
Device Regulation & Name:	21 CFR 882.4310 - Powered simple cranial drills, burrs, trephines and their accessories
Classification & Product Code: **510(k) Number:**	Class II, HBE K222391
Device Proprietary Name:	Hubly Electric Drill

Predicate Device Information:

Predicate Device:	Phasor Drill
Predicate Device Manufacturer:	Biotex Inc.
Predicate Device Common Name:	Powered Cranial Drill
Predicate Device Premarket Notification #:	K161704
Predicate Device Classification & Name:	21 CFR 882.4310 - Powered simple cranial drills, burrs, trephines and their accessories
Predicate Device Classification & Product Code:	Class II, HBE

B. Date Summary Prepared

May 4, 2023

C. Description of Device

The Hubly Electric Drill is a battery powered cranial drill. It is single-use disposable and provided ethylene oxide sterilized. The drill is designed to create optimal burr holes, in the emergency room, at the bedside, or in the operating room. The system is designed to streamline bedside intracranial access and facilitate the treatment of emergent conditions in adult patients.

The device is a battery-powered hand drill which can be used one-handed using either hand. The drill is trigger-activated after removal of the battery pull tab. The drill has a single speed and turns off when the trigger is released. The drill bit has depth indicators at 5 and 10mm depth, which the physician may use to visually gauge depth of penetration while drilling.

The drill also has an auto-stop feature which detects when the bit breaks through the inner table of the skull and immediately stops the drill. The device has an LED indicator which indicates to the user (green) when they are applying enough force and (red) when the drill stops.

The drill features mechanical plunge prevention with a tapered stainless steel drill bit. The drill may be reactivated any number of times using the trigger if the physician desires.

D. Indications for Use

The Hubly Electric Drill is a single-use, sterile, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.

E. Comparison of the Technological Characteristics

	Application Device Hubly Electric Drill - K222391	**Predicate Device Phasor Drill - K161704**	**Impact on Substantial Equivalence**
Company	Hubly, Inc.	Biotex, Inc.	N/A
Regulation Number	21 CFR 882.4310	21 CFR 882.4310	Identical
Product Code	HBE – Class II	HBE – Class II	Identical
Intended Use & Indications for use	The Hubly Electric Drill is a single-use, sterile, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.	The Phasor Drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.	Identical
Technology			
Power Source	Battery Power (removable)	Battery Power (removable)	Identical
Automatic stop	Auto-stop	None	No impact – Additional safety feature
Mechanical plunge prevention	Tapered bit	Thumbscrew depth stop	No impact
Bit Material	Stainless Steel (316)	Stainless Steel (440A)	No impact
Drill activation	Trigger – On/Off	Button – On/Off	Identical
Drill rotation	Forward	Forward & Reverse	No impact
Flute characteristics	2 Straight flutes	2-3 Twist flutes	No impact – Straight flutes remove more easily without reverse rotation.

F. Summary of Supporting Data

The Hubly Electric Drill has the same intended use, patient population and classification as the predicate. At a high level, the subject and predicate devices are based on the following same technological elements:

- Sterile packaged for single-use, and disposable
- Operates on battery power (batteries removable for disposal)
- Two state operation, single speed
- Employ mechanical plunge prevention mechanisms for safety
- Plastic drill housing with stainless steel drill bit(s)

The following technical characteristics of the subject device differ from the predicate device:

- Use of tapered drill bit for mechanical plunge prevention (vs thumbscrew depth stop)
- Drill bit diameter & length, flute type
- Addition of firmware based automatic stopping feature
- Forward-only drill functionality
- EO sterilization (vs gamma)

The Hubly drill bit is larger in diameter and tapers to the tip for mechanical plunge prevention, whereas the predicate has a thumbscrew depth stop for plunge prevention. The Hubly drill bit has straight flutes and tapers and thus is easily removed from the burr hole without reverse functionality. The applicant device has an additional firmware-based automatic stopping safety feature, and for this reason is EO sterilized.

The proposed device does not differ from the predicate in any way which would negatively impact the safety or effectiveness of the device.

G. Discussion of Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

BIOCOMPATIBILITY TESTING

The drill bit is the only patient-contacting material used in the Hubly device. 316 Stainless Steel certified to ASTM F899 was selected for its known biocompatibility with human tissues and fluids. A biological risk assessment was conducted for the device. It considers raw material, manufacturing processing, and full endpoint biocompatibility testing performed, and determines full compliance of the device with ISO 10993-1.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILTY (EMC)
Electrical safety and EMC testing were conducted on the Hubly device. The system complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 and 60601-4-2 standards for EMC.

SOFTWARE VERIFICATION TESTING
Software verification was conducted on the firmware responsible for the Hubly Electric Drill's automatic stopping feature. The device has an equivalent expected safety profile compared to the standard of care without utilizing software mitigations. The software implements additional safety features compared to the current standard of care.

The Hubly Electric Drill software is initially classified as a Class B software system according to IEC 62304 Section 4.3a based on the possible hazards to which the software component can contribute. For this reason, the resulting possible harm due to failure of software is considered non-serious. Based on the level of concern decision process (as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices), the level of concern for the Hubly Electric Drill has been determined to be "Moderate".

BENCH TESTING
The following benchtop performance tests were conducted. Results demonstrated that the drill meets all design specifications and requirements.

- Performance – battery/continuous use
- Depth of Penetration, bone thickness variation
- Bit securement
- Trigger performance
- Basic Safety and Essential Performance
- EMC Testing (Basic Safety, Essential Performance, Electromagnetic disturbances)

ANIMAL STUDY
In the GLP animal study conducted, design validation and summative usability evaluation were conducted. A sheep model was selected for its close approximation of the characteristics of the human skull. This study demonstrated that Users (Test Device Evaluators) could safely use the Hubly Electric Drill for intracranial access without damaging the dura or brain tissue. Additionally, all *in vivo* requirements were met to support Usability Evaluation for the Hubly electric Drill.

CLINICAL STUDIES
Clinical testing was not performed on human subjects.

H. Conclusion

The predicate device was cleared based on bench testing alone. The performance and design validation testing conducted on the Hubly Electric Drill on the bench and in animals demonstrates that it performs equivalent to the predicate device that is currently marketed for the same intended use. The proposed device adds additional control and safety features, and hardware and

software verification and validation demonstrate that the Hubly drill will perform as safe and effective as the predicate device.