November 6, 2025

Hubly, Inc.
Julie Byars
Quality Lead
815 Ogden Ave.
Lisle, Illinois 60532

Re: K250815
Trade/Device Name: Hubly 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: October 3, 2025
Received: October 8, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2025.11.06 17:02:01 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250815

Device Name

Hubly Auto-Stop Drill (H100)

Indications for Use *(Describe)*

The Hubly Auto-Stop Drill (H100) is a single-use, sterile, disposable device intended for use on adult patients during laminectomy and laminotomy procedures for drilling holes through the lamina.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

A. Device Information:

Category	Comments
Sponsor:	Hubly, Inc. Casey Qadir 815 Ogden Ave. Lisle, IL 60532 (844) 482-5942
Correspondent Contact Information:	Julie Byars 815 Ogden Ave. 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 K250815
Device Proprietary Name:	Hubly Auto-Stop Drill

Predicate Device Information:

Predicate Device:	Hubly Electric Drill
Predicate Device Manufacturer:	Hubly, Inc
Predicate Device Common Name:	Powered Cranial Drill
Predicate Device Premarket Notification #:	K230619
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

November 6, 2025

C. Description of Device

The Hubly Drill is a battery powered drill. It is single-use disposable and provided ethylene oxide sterilized. The drill is designed to create optimal holes in bone. For trephination procedures the Hubly Drill is intended to drill cranial bone and create burr holes in the emergency room, at the bedside, or in the operating room. For laminectomy and laminotomy procedures the drill is intended to be used in the operating room to drill holes through the lamina to facilitate excision of the lamina.

The drill can be used one-handed using either hand. It 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 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.

The drill also has an auto-stop feature which detects when the bit breaks through the bone 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.

D. Indications for Use

The Hubly Auto-Stop Drill (H100, H200, H201, H0270, H0271, H0272) is a single-use, sterile, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.

The Hubly Auto-Stop Drill (H100) is a single-use, sterile, disposable device intended for use on adult patients during laminectomy and laminotomy procedures for drilling holes through the lamina.

E. Comparison of Technological Characteristics

	Application Device Hubly Drill – K250815	**Predicate Device Hubly Electric Drill – K230619**	**Impact on Substantial Equivalence**
Company	Hubly, Inc.	Hubly, 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 Auto-Stop Drill (H100, H200, H201, H0270, H0271, H0272) is a single-use, sterile, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone. The Hubly Auto-Stop Drill (H100) is a single-use, sterile, disposable device intended for use on adult patients during laminectomy and laminotomy procedures for drilling holes through the lamina.	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.	Minor Impact – Addition of laminectomy and laminotomy indication. No impact on intended use, safety or effectiveness.
Technology – THE PROPOSED DRILL IS THE SAME AS THE PREDICATE, WITH AN ADDED INDICATION.			

Power Source	Battery Power (removable)	Battery Power (removable)	Identical
Automatic stop	Auto-stop	Auto-stop	Identical
Mechanical plunge prevention	Tapered bit	Tapered bit	Identical
Bit Material	Stainless Steel (316)	Stainless Steel (316)	Identical
Drill activation	Trigger – On/Off	Trigger – On/Off	Identical
Drill rotation	Forward	Forward	Identical
Flute characteristics	2 Straight flutes	2 Straight flutes	Identical

F. Discussion of Non-Clinical 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 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 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 FDA Guidance document "Guidance for the Content of Premarket Submissions for Device Software Functions" the documentation level for the Hubly Drilling System has been determined to be "Basic Documentation".

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)

Additional performance testing was completed using sawbones absolute sheets as representative lamina bone to demonstrate that the drill performance using cranial bone is equivalent to the drill performance on sawbones absolute sheets. Drill penetration depth was evaluated on the sawbones sheets with thicknesses from 2mm-5mm. A representative dural model was evaluated for damage at each of the thicknesses. Testing was performed to characterize the force needed to activate the auto-stop feature during drilling as well as the magnitude of the current spike needed to trigger the stopping signal.

Testing was performed to characterize the performance of the Hubly Drills ability to drill into the lamina, and to evaluate the thickness and range of angles required for drilling.

Alternate bone testing was performed to verify that there was not a significant difference in the Hubly Drilling System penetration depth performance between bovine and cranial bone.

A cadaver study was conducted to validate that the Hubly Drilling System is as safe as the standard of care for the laminectomy and laminotomy indication.

A second cadaver study was conducted to validate that the Hubly Drilling System is as safe as the standard of care and to further characterize the safety of the drill performance in the lamina.

A summative usability study was conducted to confirm that users can effectively perform critical tasks for the Hubly Drilling System for laminectomy and laminotomy procedures and that the use-related risks are at an acceptable level.

A literature review was conducted to characterize the material properties and disease state conditions of the human lamina and spinal dura. The report identified the density, thickness, hardness, elastic modulus, and angles of human lamina.

G. Discussion of Clinical Performance Testing

ANIMAL STUDY
Animal testing was not performed.

CLINICAL STUDIES
Clinical testing was not performed.

H. Conclusion

The performance and design validation testing conducted on the Hubly Drill demonstrates that it performs comparably to the predicate device for the added indication for laminectomy and laminotomy procedures. All hardware and software verification and validation demonstrate that the Hubly Drill will perform as safe and effective as the predicate.