March 6, 2024

Evonos GmbH & Co. KG
Jörg Mans
CEO
Stockacher Strasse 134
Tuttingen, Baden-Württemberg 78532
Germany

Re: K231403
Trade/Device Name: evoDrill Cranial Perforator
Regulation Number: 21 CFR 882.4305
Regulation Name: Powered Compound Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBF
Dated: December 8, 2023
Received: December 8, 2023

Dear Jörg Mans:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2024.03.06 17:22:17 -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K231403

Device Name
evoDrill Cranial Perforator

Indications for Use *(Describe)*

The evoDrill Cranial Perforators are single-use surgical devices for cranium perforation. The perforators with the 3mm step automatically release and stop perforating at cranial bone thickness of at least 3mm. The perforators with the 1mm step automatically release and stop perforating at cranial bone thickness of at least 1mm.

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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510(k) Summary

Date Prepared: March 6, 2024

Owner's Name (21 CFR 807.92(a)(1):

Company Name:	evonos GmbH & CO. KG
Company Address:	Stockacher Strasse 134 D-78532 Tuttlingen, Germany
Contact Person:	Jörg Mans
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Email-Address:	j.mans@evonos.de

Trade Name, Common Name, Classification (21 CFR 807.92(a)(2))

Device Trade Name:	evonos evoDrill Cranial Perforator
Device Common Name:	Disposable Cranial Perforator
Device Classification Name:	Drills, Burrs, Trephines & Accessories (Compound, Powered)
Device Classification:	Class II
Classification Code:	HBF
Regulation Number:	21 CFR 882.4305

Predicate Device Names (21 CFR 807.92(a)(3))

- Acra Cut Automatic Cranial Drill (DGR-1 #200-241; DGR-II #200-251) (K892866) (Primary)
- Codman Disposable Perforators 26-1221 (K933894)

DEVICE DESCRIPTION

The evonos evoDrill cranial perforator are single-use devices for trephining the cranial bone. The perforators have an automatic stop mechanism that stops the trephination process as soon as the skull bone has been pierced. The two variants evoDrill cranial perforator 3-flutes and evoDrill cranial perforator 4-flutes are available in two versions that are suitable for different bone thicknesses.

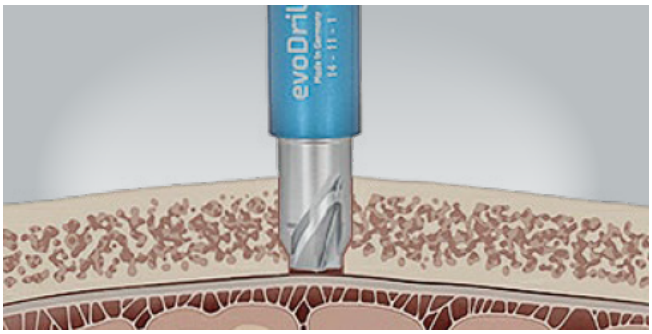
The first version is used from bone thicknesses of 3mm, the second version is used for trepanation with bone thicknesses between 1mm and 3mm. Both variants are available in four different diameters.

Item Number	Item Description	Inner Diameter	Outer Diameter	Bone Thickness
26-000002	evoDrill Cranial Perforator 9/6/1mm, 3-flutes	6mm	9mm	1-3mm
26-000003	evoDrill Cranial Perforator 9/6/3mm, 3-flutes	6mm	9mm	> 3mm
26-000004	evoDrill Cranial Perforator 11/7/1mm, 3-flutes	7mm	11mm	1-3mm
26-000005	evoDrill Cranial Perforator 11/7/3mm, 3-flutes	7mm	11mm	> 3mm
26-000006	evoDrill Cranial Perforator 13/9/1mm, 3-flutes	9mm	13mm	1-3mm
26-000007	evoDrill Cranial Perforator 13/9/3mm, 3-flutes	9mm	13mm	> 3mm
26-000008	evoDrill Cranial Perforator 14/11/1mm, 3-flutes	11mm	14mm	1-3mm
26-000009	evoDrill single use, Ø14/11mm, 3mm, 3-flutes	11mm	14mm	> 3mm

Item Number	Item Description	Inner Diameter	Outer Diameter	Bone Thickness
26-409061	evoDrill Cranial Perforator 9/6/1mm, 4-flutes	6mm	9mm	1-3mm
26-409063	evoDrill Cranial Perforator 9/6/3mm, 4-flutes	6mm	9mm	> 3mm
26-411071	evoDrill Cranial Perforator 11/7/1mm, 4-flutes	7mm	11mm	1-3mm
26-411073	evoDrill Cranial Perforator 11/7/3mm, 4-flutes	7mm	11mm	> 3mm
26-413091	evoDrill Cranial Perforator 13/9/1mm, 4-flutes	9mm	13mm	1-3mm
26-413093	evoDrill Cranial Perforator 13/9/3mm, 4-flutes	9mm	13mm	> 3mm
26-414111	evoDrill Cranial Perforator 14/11/1mm, 4-flutes	11mm	14mm	1-3mm
26-414113	evoDrill Cranial Perforator 14/11/3mm, 4-flutes	11mm	14mm	> 3mm

Table 1: Item Description

The evonos evoDrill cranial perforator per CFR, Part 882.4305, is a bone cutting and drilling instrument driven by a pneumatic or electric surgical motor in order to drill burr holes through the skull of a patient. The evonos evoDrill cranial perforator are devices similar in design and construction to other cranial perforators currently on the market; (e.g.: Acra Cut Automatic Cranial Drill DGR-1 #200-241; DGR-II #200-251 and Codman Disposable Perforators 26-1221, 26-1222, 26-1223). The evonos evoDrill cranial perforator requires a motor and an attached or integrated speed reducer in order to run the perforators at a speed range of 800 RPM to 1500 RPM.



Picture 1: Schematic illustration of the bone perforation

INDICATIONS FOR USE

The evoDrill Cranial Perforators are single-use surgical devices for cranium perforation. The perforators with the 3mm step automatically release and stop perforating at cranial bone thickness of at least 3mm. The perforators with the 1mm step automatically release and stop perforating at cranial bone thickness of at least 1mm.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device	**evoDrill**	**Codman Cranial Perforator**	**AcraCut Cranial Perforator**
Manufacturer	evonos GmbH & Co. KG	Codman	AcraCut
510(k) Number	K231403 (subject device)	K933894 (Predicate Device)	K892866 (Predicate Device)
Indications For Use	The evoDrill Cranial Perforators are single-use surgical devices for cranium perforation. The perforators with the 3mm step automatically release and stop perforating at cranial bone thickness of at least 3mm. The perforators with the 1mm step automatically release and stop perforating at cranial bone thickness of at least 1mm.	The Codman disposable Perforator is for use in perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.	The Acra Cut DGR-I, DGR-II and DGR-0 are designed to automatically release and stop upon penetration of bone that is at least 3mm thick. The DGR-II perforator is for use at thin skull areas such as pediatric, temporal and suboccipital areas. Thea are designed to automatically release and stop upon penetration of bone as thin as 1mm.
Material	Plastic/ stainless steel / Aluminium	Plastic/ stainless steel	Plastic/ stainless steel
Fittings	Hudson	Hudson	Hudson

Device	evoDrill	Codman Cranial Perforator	AcraCut Cranial Perforator
Manufacturer	evonos GmbH & Co. KG	Codman	AcraCut
510(k) Number	K231403 (subject device)	K933894 (Predicate Device)	K892866 (Predicate Device)
Prinicpal of operation	similar	similar	similar
Cutting Performance	similar	similar	similar
Burr hole diameter	14/11mm; 13/9mm; 11/7mm; 9/6mm	14/11 mm; 11/8mm; 9/6mm	14/11mm; 13/9mm; 11/7mm
Bone Thicknesses	1mm and thicker	3mm and thicker	1mm and thicker
Release mechanism	Automatic spring-loaded release mechanism; The inner drill is coupled with the housing once an axial force is applied on the fitting and the tip of the drill has to overcome resistance (bone), so that the resistance is higher than the spring force of the couple mechanism. Once the inner drill has pierced the skull bone, the resistance drops so that the spring pressure is higher than the resistance and the inner drill is decoupled	Similar Automatic spring-loaded release mechanism; The inner drill is coupled with the housing once an axial force is applied on the fitting and the tip of the drill has to overcome resistance (bone), so that the resistance is higher than the spring force of the couple mechanism. Once the inner drill has pierced the skull bone, the resistance drops so that the spring pressure is higher than the resistance and the inner drill is decoupled	Similar Automatic spring-loaded release mechanism; The inner drill is coupled with the housing once an axial force is applied on the fitting and the tip of the drill has to overcome resistance (bone), so that the resistance is higher than the spring force of the couple mechanism. Once the inner drill has pierced the skull bone, the resistance drops so that the spring pressure is higher than the resistance and the inner drill is decoupled
Rotation speed	800 – 1500 rpm	800 – 1200 rpm	800 – 1200 rpm
How supplied	Sterile Sterilized by Radiation	Sterile Sterilized by Radiation	Sterile Sterilized by Radiation
Number of Cutting Flutes	3 / 4	4	4

Table 2: Device Comparison

Based on the information summarized above, the proposed evoDrill Cranial Perforators are similar to the currently marketed predicate and reference devices in indications for use, design, principle of operation and device material. All perforators are supplied in sterile condition, sterilized using radiation and for single use only.

PERFORMANCE TESTING

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

Test	Method	Results
Biocompatibility	The device is classified as an externally communicating devices in contact with tissue/bone for a limited duration (≤24hr). Biocompatibility testing was addressed in accordance with ISO 10993 as described in FDA's Biocompatibility Guidance.	All biocompatibility testing confirmed that the device fulfills the biocompatibility requirements considering contact area and duration.
Sterilization and packaging validation testing	Sterilization validation testing in accordance with ISO 11137-1, ISO 11137-2, ISO 11607-1 and ISO 11607-2.	All tested specimen confirm that devices are sterile and the SAL of 10^{-6} is met. Shelf-Life validation confirmed the integrity of the product and packaging of the defined shelf-life, labeled on the device.

Test	Method	Results
Cutting Performance	The performance of the subject device was evaluated for automatic stop function mechanism, maximum number of uses, drilling time and device geometry for establishing substantial equivalency to the predicate.	All tested specimen confirmed that the overall cutting performance related to the autostop function mechanism, drilling time and surface structure fulfilled the acceptance criteria

Table 3: Performance Testing

CONCLUSION

Based on the similarities of the intended use/indications for use, technological and functional characteristics, and the results of the non-clinical performance testing, the evonos evoDrill Cranial Perforators, are substantially equivalent to the predicate devices.