June 20, 2022

EMD Endoszkop Muszer Gyarto es Kereskedelmi Kft.
Gergo Ujvari
Export Manager
Bartok Bela u. 113/B
Debrecen, Hajdu-Bihar 4031, Hungary

Re: K213228
Trade/Device Name: NeuroLine Disposable Cranial Perforator with Hudson end
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: May 13, 2022
Received: May 16, 2022

Dear Gergo Ujvari:

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, 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)*
K213228

Device Name
NeuroLine Disposable Cranial Perforator with Hudson End

Indications for Use *(Describe)*
NeuroLine perforators are designed to make holes in the skull bone. The perforators have an integrated safety mechanism that releases automatically after passing through the bone and stops drilling.

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

Date Prepared: June 14, 2022

Applicant:

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Contact Person:

Gergo Ujvari – International Sales Manager

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Trade Name: NeuroLine Disposable Cranial Perforator with Hudson End

Common Name: Disposable Cranial Perforator

Classification name: 21CFR section 882.4305

Product Code: HBF

Device Classification: Class II

Predicate Device:

ACRA-CUT Standard and Disposable Cranial perforator	K833266

Reference Device:

EasyDrill Autostop Cranial Perforator	K141455

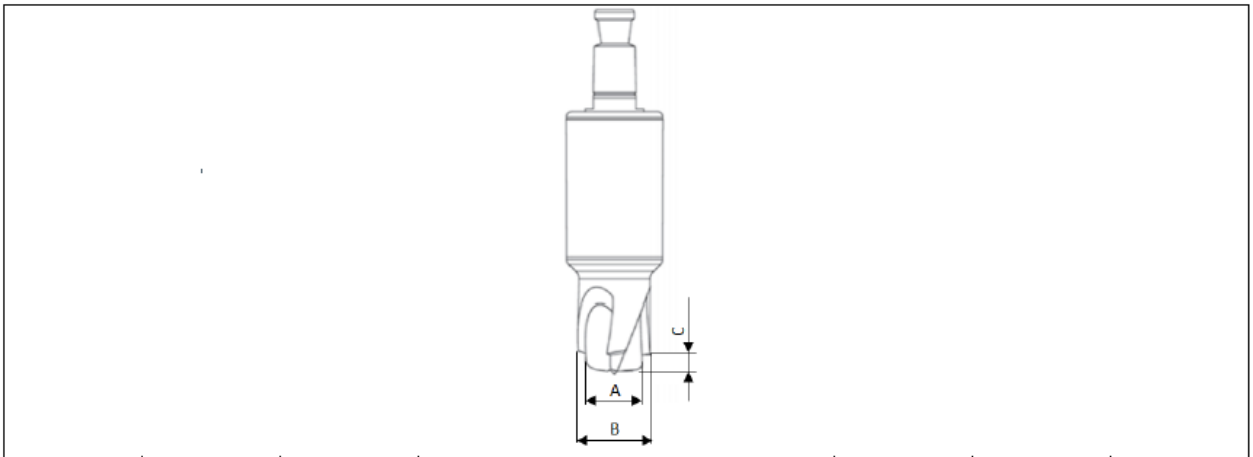
Device Description:

The NeuroLine Disposable Cranial perforators (NLO-x/y-z) are single-use cutting devices that are packaged sterile and are used to perforate the skull bone. The perforator functions automatically, which means that it employs a clutch mechanism to automatically disengage once perforation is accomplished and as the drill ceases to find resistance to bone.

The perforator has Hudson type connection and can connect to all the driver units with Hudson connection.

Perforators are offered in three different sizes: 6/9 mm, 7/11 mm, 9/13 mm and 11/14 mm. Sizes indicate hole diameters to be made by perforators in millimeters.

Perforators are also differentiated based on the thickness of skull bone. The NLO-x/y-3.0 perforators are used on skulls at least 3 mm thick, whereas NLO-x/y-1.5 ones are used on skulls at least 1.5 mm thick.



Models	NLO-6/9-1.5	NLO-7/11-1.5	NLO-9/13-1.5	NLO-11/14-1.5	NLO-6/9-3.0	NLO-7/11-3.0	NLO-9/13-3.0	NLO-11/14-3.0
A [mm]	6	7	9	11	6	7	9	11
B [mm]	9	11	13	14	9	11	13	14
C [mm]	1.5	1.5	1.5	1.5	3	3	3	3
Application	for use on skulls at least 1.5mm thick				for use on skulls at least 3mm thick			

Indications for Use:

NeuroLine perforators are designed to make holes in the skull bone. The perforators have an integrated safety mechanism that releases automatically after passing through the bone and stop drilling.

Comparison of technology characteristics

Device	NeuroLine Disposable Cranial Perforator with Hudson End	ACRA-CUT Standard and Disposable Cranial Perforator	EasyDrill Autostop Cranial Perforator
Manufacturer	EMD Endoszkop Muszer Gyartoes Kereskedelmi Kft.	Acra-Cut Inc.	Micromar Industria e Comercio Ltda.
510(k) number	K213228 (Subject Device)	K833266 (Predicate Device)	K141455 (Reference Device)
Specified hole sizes	6/9 mm, 7/11 mm, 9/13mm, 11/14 mm	Similar	6/9 mm, 7/11 mm, 11/14 mm
Indication for use	NeuroLine perforators are designed to make holes in the skull bone. The perforators have an integrated safety mechanism that releases automatically after passing through the bone and stops drilling.	Similar	The EasyDrill Cranial Perforator is a sterile, single use cutting device intended for performing cranial bone trephination.
Operating principles	Same	Same	Same
Device Material	Stainless steel	Similar	Stainless steel

Sterilization	Sterile (Gamma Radiation)	Sterile	Sterile (Gamma Radiation)
Reusable /Single Use	Single Use	Similar	Single Use

Based on the information summarized above, the proposed NeuroLine Disposable Cranial Perforator and with Hudson end are similar to the currently marketed predicate and reference devices in indications for use, design, principle of operation and device material. All perforators are offered sterile.

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.	Pass
Sterilization and packaging validation testing	Sterilization validation testing in accordance with ISO 11137-1, ISO 11137-2, ISO 11607-1 and ISO 11607-2.	Pass
Bench Testing	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.	Pass

Conclusions

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 NeuroLine Disposable Cranial Perforator with Hudson end, are substantially equivalent to the predicate device, ACRA-CUT Standard and Disposable Cranial perforator.