DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 16, 2015

Micromar Industria e Comercio Ltda.
% Deep Pal
US Agent- Principal Regulatory Affairs Specialist
Medtronic Powered Surgical Solutions
4620 North Beach Street
Fort Worth, Texas 76137

Re: K141455
Trade/Device Name: EasyDrill Autostop 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: February 12, 2015
Received: February 13, 2015

Dear Deep Pal,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141455

Device Name
EasyDrill Autostop Cranial Perforator

Indications for Use *(Describe)*
The EasyDrill Autostop Cranial Perforator is a sterile, single use cutting device intended for performing cranial bone trephination.

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

This summary is submitted in accordance with the requirements of 21CFR807.92.

DATE PREPARED
March 16, 2015

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PROPRIETARY NAME
EasyDrill Autostop Cranial Perforator

COMMON/USUAL NAME
Cranial Perforator

CLASSIFICATION NAME
Powered compound cranial drills, burrs, trephines, and their accessories, HBF, 21CFR882.4305

PREDICATE DEVICE IDENTIFICATION
K071931: Codman Disposable Perforator, Codman & Shurtleff, Inc.
K082010: Zyphr Disposable Cranial Perforator, Stryker Instruments
K892866: Acra-Cut Disposable Cranial Perforator, Acra-Cut Inc.

DEVICE DESCRIPTION

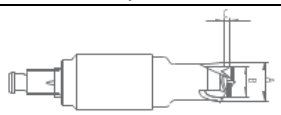
The EasyDrill Autostop Cranial Perforator comprises of an Inner and Outer Drill, and a Hudson Shank that is designed to lock onto a Pneumatic or an Electric Drill Motors.

The EasyDrill Autostop Cranial Perforator device is a bone cutting and drilling instrument used in conjunction with a surgical motor and a Hudson Chuck - speed reducer attachment, to drill access holes through a patient's skull. When properly used, the EasyDrill Autostop Cranial Perforator employs a clutch mechanism to automatically disengage once perforation is accomplished and as the drill ceases to find resistance to bone.

The EasyDrill Autostop Cranial Perforator is a mechanically powered tool, designed to create an access hole through the skull. The subject Perforator device derives its mechanical torque and rotational speed from various legally marketed Electric and/or Pneumatic Drill Motors. The EasyDrill Autostop Cranial Perforator device is latched onto a Hudson Chuck device, which is in turn attached to the Drill Motors.

The EasyDrill Autostop Cranial Perforator is provided Gamma Sterilized, in a sealed packaging and is designed for single patient use only.

EasyDrill Autostop Cranial Perforator



Model	External Diameter	Internal Diameter	Shelf	Color	**Minimum Bone Thickness**
Ø9 x Ø6 x **3mm**	9 mm	6 mm	3 mm	Yellow	**3.25 mm**
Ø11 x Ø7 x **3mm**	11	7	3	Blue	**3.25 mm**
Ø14 x Ø11 x **3mm**	14	11	3	White	**3.25 mm**
Ø14 x Ø11 x **1.5mm**	14	11	1.5	Green	**1.75 mm**

INDICATIONS FOR USE

The EasyDrill Autostop Cranial Perforator is a sterile, single use cutting device intended for performing cranial bone trephination.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Mechanically powered tool, designed to create an access hole through the skull is the technological principle for both the subject and predicate devices. It is based on the use of powered instrumentation for deriving the needed mechanical torque and rotational speed for cranial bone trephination. At a high level, the subject and predicate devices are based on the following same technological elements:

- Cranial Perforator Application: Used for cranial bone trephination;
- Used in conjunction with Electric and/or Pneumatic Drill System and a Hudson Chuck - Speed Reducer Attachment: Comprises of an Inner and Outer Drill, and a Hudson Shank that is designed to lock onto a Pneumatic or an Electric driving tool. This allows the device to derive the needed mechanical torque and rotational speed to create an access hole through the skull;
- Clutch Mechanism: Automatically disengages once perforation is accomplished and as the drill ceases to find resistance to bone.

In terms of the materials used in manufacturing of the patient contacting components of the subject EasyDrill Autostop Cranial Perforator devices, the subject EasyDrill Autostop Cranial Perforator device is similar to the predicate devices. Like the predicate devices, the patient contacting Central and the Outer Drill components of the EasyDrill Autostop Cranial Perforator devices are made from Stainless Steel materials.

PERFORMANCE TESTING

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

CADAVER STUDY

In order to evaluate the performance, its application and suitability of the subject EasyDrill Autostop Cranial Perforator devices for its intended use, the EasyDrill Autostop Cranial Perforator devices were tested under simulated use conditions on human cadaveric specimen - skull. Results of cadaveric testing demonstrate that the EasyDrill Autostop Cranial Perforator does not present any new issues of safety or effectiveness, and that the devices perform as intended during cranial bone trephination.

SIDE BY SIDE BENCH TOP TESTING

In order to evaluate the performance of the subject EasyDrill Autostop Cranial Perforator devices against the predicate devices, for its intended use, the EasyDrill Autostop Cranial Perforator devices were tested alongside the predicate devices in a Bovine Scapula.

ENDOTOXIN TESTING

The subject EasyDrill Autostop Cranial Perforator devices were tested for Endotoxins using the Limulus Amebocyte Lysate (LAL) Gel-Clot test procedure. The data from the study show that the subject EasyDrill Autostop Cranial Perforators meet the required endotoxin specification limit of 2.15 EU/Device.

CONCLUSIONS

The performance data from the side-by-side testing, of the subject EasyDrill Autostop Cranial Perforator device against the predicate perforator devices, were compared to support the safety of the subject device and the cadaver study demonstrates that the subject EasyDrill Autostop Cranial Perforator should perform as intended in the specified use conditions.