



August 23, 2022

Biomet Micofixation
% Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K213072

Trade/Device Name: 2.1 x 255mm Drill, 22mm Stop
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: July 19, 2022
Received: July 20, 2022

Dear Christine Scifert:

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

Indications for Use

510(k) Number (if known)

K213072

Device Name

2.1 x 255mm Drill, 22mm Stop

Indications for Use (Describe)

The Lorenz Twist Drills are intended to be used for drilling holes in bone during neurosurgical procedures.

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
2.1 x 255mm Drill, 22mm Stop
August 23, 2022

Company: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Company Contact: Mark Wladkowski
mark.wladkowski@zimmerbiomet.com
(904) 362-3940

Official Correspondent: Christine Scifert
Christine.Scifert@askmrcglobal.com
(901) 831-8053

Trade Name: 2.1 x 255mm Drill, 22mm Stop

Common Name: Drills, Burrs, Trephines & Accessories (Simple, Powered)

Classification: Class II

Regulation Number: 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories

Panel: Neurology

Product Code: HBE

Device Description:

Biomet Microfixation Twist drills are drill bits which can either be attached to a manual instrument handle or attached to a powered handpiece/drill motor and used to drill holes in bone.

The subject submission seeks to add the 2.1 x 255mm Drill, 22mm Stop to the Lorenz Twist Drills family to be used in neurosurgical procedures.

2.1 x 255mm Drill, 22mm Stop manufactured from medical grade stainless steel per ASTM F899. The subject drill bit is intended for single use only and is provided non-sterile, to be sterilized by the end-user prior to use.

Indications for Use:

The Lorenz Twist Drills are intended to be used for drilling holes in bone during neurosurgical procedures.

Substantial Equivalence:

The subject device is substantially equivalent to the following predicate device:
Walter Lorenz Surgical, Inc; Lorenz Twist Drills – K062842

The subject and predicate devices are similar in Intended Use, Technological Characteristics, and Material.

Characteristic	SUBJECT: 2.1 x 255mm Drill, 22mm Stop	Primary Predicate: Walter Lorenz Surgical, Inc. (now Biomet Microfixation) Lorenz Twist Drills
510(k) Number	SUBJECT	K062842
Intended Use	Drills, Burrs, Trephines & Accessories (Simple, Powered)	Drills, Burrs, Trephines & Accessories (Simple, Powered)
Product Code	HBE	HBE
Indications for Use	The Lorenz Twist Drills are intended to be used for drilling holes in bone during neurosurgical procedures.	The Lorenz Twist Drills are intended to be used for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.
Materials	Stainless Steel per ASTM F899	Stainless Steel
Geometry and Dimensions	Diameter: 2.1mm Length: 255mm	Diameters: 1.0-2.9mm Lengths: 22-115mm
Sterility	Non-sterile	Non-sterile

Performance Testing:

Mechanical testing, including Static Cantilever Bend Testing, Static Torsion Testing, and Lifecycle testing, have been performed on the subject 2.1 x 255mm Drill, 22mm Stop and the results have shown them to be substantially equivalent to the predicate device.

Conclusion:

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate device.