November 15, 2022

Biomet Microfixation
% Danielle Besal
Principal Consultant
MRC Global, LLC
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K223199
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: October 13, 2022
Received: October 13, 2022

Dear Danielle Besal:

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 -S

Digitally signed by Adam D. Pierce -S
Date: 2022.11.15 11:27:20 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
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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)*
K223199

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.

510(k) Summary
2.1 x 255mm Drill, 22mm Stop
November 15, 2022

Company:	Biomet Microfixation 1520 Tradeport Drive Jacksonville, FL 32218
Company Contact:	Jay Sharma Jay.Sharma@zimmerbiomet.com Phone: (904) 741-4400
Official Correspondent:	Danielle Besal Danielle.Besal@askmrcglobal.com Phone: (901) 827-8670

510(k) Number:	K223199
Trade Name:	2.1 x 255mm Drill, 22mm Stop
Predicate Device:	K213072 - 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 in neurosurgical procedures. The 2.1 x 255mm Drill, 22mm Stop is 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. The subject submission seeks to add the compatibility of the 2.1 x 255mm Drill, 22mm Stop drill with neurosurgical stereotactic instrument systems.

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 predicate Biomet Microfixation; 2.1 x 255mm Drill, 22mm Stop (K213072). The subject and predicate devices are identical in intended use, technological characteristics, and materials. The addition of compatibility with

stereotactic instruments does not raise different questions of safety and effectiveness as they are intended for use with generic instrumentation, such as the subject drill, and this compatibility does not impact the drill's intended use or mechanism of action.

Performance Testing:

Tolerance analysis and summative usability testing were conducted on the subject device and successfully verified and validated compatibility with stereotactic instrument systems.

Test	Test Method Summary	Results
Tolerance Analysis	Dimensional analyses were conducted to determine if the drill is compatible with the neurosurgical stereotactic placement devices.	The tolerance analyses showed that the subject device dimensions are compatible with the dimensions of the neurosurgical stereotactic placement devices; thus, the subject drill bit mates effectively.
Summative Usability Validation	Summative usability evaluations were conducted in accordance with IEC 62366-1:2015+A1:2020.	The acceptance criteria were met and the results demonstrated the subject device can be used safely and effectively with neurosurgical stereotactic instrument

Conclusion:

Based on the summary of design control activities, the subject device is determined to be substantially equivalent to the predicate device.