December 23, 2021

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

Re: K213208
Trade/Device Name: Twist Drills
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 26, 2021
Received: October 27, 2021

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, 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)*
K213208

Device Name
Twist Drills

Indications for Use *(Describe)*
Biomet Microfixation Twist Drills are intended for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Twist Drills
510(k) Summary

A. Device Information

Category		Comments
Sponsor		Biomet Microfixation 1520 Tradeport Dr Jacksonville FL 32218 (904)362-3940
Correspondent Contact		Danielle Besal Principal Consultant | MRC Global Danielle.Besal@askmrcglobal.com (901)827-8670
Device Common Name		Drill bit
Device Regulation & Name	Primary	888.4310: Powered simple cranial drills, burrs, trephines, and their accessories
	Secondary	882.4300: Manual cranial drills, burrs, trephines, and their accessories 872.4120: Bone cutting instrument and accessories 878.4800: Manual surgical instrument for general use 878.4820: Surgical instrument motors and accessories/ attachment 888.4540: Orthopedic manual surgical instrument
Classification & Product Code	Primary	Class 2: HBE
	Secondary	Class 2: HBG, DZI Class 1: HTZ, GFG, HTW
510(k) Number		K213208
Device Proprietary Name		Twist Drills

Predicate Device Information

Predicate Device	Twist Drills
Predicate Device Manufacturer	Biomet Microfixation
Predicate Device Common Name	Drill bit
Predicate Device 510(k)	K062842
Predicate Device Classification & Name	882.4310: Powered simple cranial drills, burrs, trephines, and their accessories 882.4300: Manual cranial drills, burrs, trephines, and their accessories 872.4120: Bone cutting instrument and accessories 878.4800: Manual surgical instrument for general use 878.4820: Surgical instrument motors and accessories 888.4540: Orthopedic manual surgical instrument
Predicate Device Classification & Product Code	Class 2: HBE, HBG, DZI Class 1: HTZ, GFG, HTW

B. Date Summary Prepared

December 21, 2021

C. Description of Device

Biomet Microfixation manufactures and distributes a variety of single use twist drills to aid in the implantation of Biomet Microfixation implants. Biomet Microfixation Twist Drills are intended for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures. The drills are manufactured from Stainless Steel. Some drills contain flutes along the majority of the drill length, while others contain a "stop" feature which prevents further drilling past a designated length. Additionally, some drills contain an "adjustable stop" feature which allows to surgeon to set the stop length intraoperatively. Twist Drills are distributed non-sterile and are intended for single-patient use. Cleaning should only be performed on new or uncompromised drills. The drills should be steam sterilized by the health-care facility prior to use.

D. Indications for Use

Biomet Microfixation Twist Drills are intended for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.

E. Comparison of the Technological Characteristics

Characteristic		**Subject Device Twist Drills K213208**	**Predicate Device Twist Drills K062842**	**Impact on Substantial Equivalence**
Company		Biomet Microfixation	Biomet Microfixation	Identical
Regulation Number		882.4310, 882.4300, 872.4120, 878.4800, 878.4820, 888.4540	882.4310, 882.4300, 872.4120, 878.4800, 878.4820, 888.4540	Identical
Product Code		HBE, HBG, DZI, HTZ, GFG, HTW	HBE, HBG, DZI, HTZ, GFG, HTW	Identical
Indications for Use		Biomet Microfixation Twist Drills are intended for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.	Biomet Microfixation Twist Drills are intended for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.	Identical
Material		Stainless steel	Stainless steel	Identical
Sizing	Diameter	0.7-2.5mm	0.7-2.7mm	Substantially equivalent; longer length supported by design verification and validation.
	Length	0.866-6.818 in	0.866-4.528 in	
Drill working ends		5 types	5 types	Identical
Drill connection ends		10 types	7 types	Substantially equivalent; additional

			connection end designs supported by design verification and validation.
Drill stops	Fixed or adjustable	Fixed	Substantially equivalent; adjustable stop design supported by design verification and validation.
Sterilization	End user steam sterilization	End user steam sterilization	Identical
Use	Single use	Single use	Identical

F. Summary of Supporting Data

Design verification and validation testing were performed on the subject devices. Clinical data was not required for the determination of substantial equivalence.

G. Discussion of Performance Testing

The results from all design verification and validation tests confirmed that the subject devices met the predetermined acceptance criteria. Thus, the minor differences in technological characteristics versus the predicate (longer lengths, additional connection end designs, and adjustable stop feature) do not raise any new questions or safety and effectiveness and the subject devices are at least as safe and effective as the predicate.

H. Conclusion

The subject devices are substantially equivalent to the predicate Twist Drills (K062842). The subject components are identical in indications and materials, and similar in sizing, geometry, and features to the predicate devices. The minor differences in technological characteristics between the subject and predicate devices do not raise any new questions of safety and effectiveness and the subject device is at least as safe and effective as the predicate. It is concluded that subject Twist Drills are substantially equivalent to the predicate devices.