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

December 1, 2016

Biotex, Inc.
Manish Ahuja
Director Of Engineering and Product Development
114 Holmes Rd
Houston, Texas 77045

Re: K161704
Trade/Device Name: Phasor Drill
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: June 20, 2016
Received: June 20, 2016

Dear Mr. Ahuja:

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,

Michael J. Hoffmann -A

for 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)*
K161704

Device Name
Phasor Drill

Indications for Use *(Describe)*
The Phasor Drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Phasor™ Drill device is provided below.

Device Common Name:	Bone Drill
Device Proprietary Name:	Phasor™ Drill
Submitter:	Biotex, Inc. 114 Holmes Rd. Houston, Texas 77045
Contact:	Manish Ahuja Director of Engineering and Product Development 114 Holmes Rd. Houston, Texas 77045 manish@biotexmedical.com
Date Prepared:	November 1, 2016
Classification Regulation:	21 CFR 882.4310
Panel:	Neurological
Product Code:	HBE
Predicate Device	K014060- MicroAire®1000E System MicroAire® Surgical Instruments K962913- Sterile Drill Bits Synthes, Inc.
Indication for Use	The Phasor Drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.

Device Description

The Phasor™ Drill is a handheld single unit drill that is a sterile, single use device. The drill includes an ergonomically designed outer shell for ease and maneuverability, a thumbscrew drill stop to ensure the product drills to the preset required depth, and a fixed drill bit made from 440A stainless steel. The Phasor™ Drill is powered by six primary lithium CR2 cells electrically connected in series to provide 18 V. The motor used in the Phasor™ Drill is a brushed DC motor which is designed to be run from a direct current power source, via batteries. The gearbox is integrated into the motor to reduce the rotational speed. The drill bit forms the shaft of the motor eliminating the need for a coupling, chuck or other clutching mechanism. The Phasor™ Drill product family includes various drill sizes depending on the drill bit diameter (0.75-3.2 mm), number of flutes (2 or 3), drill bit length (75-210 mm), and Thumb Screw Drill stop diameters (1.5-3.2 mm). As seen in *Figure 1*, the Phasor™ Drill has two switches. The ON/OFF button in the front is a momentary push button switch which activates the drill when pressed. The blue slider switch on the top is used for reversing the direction of rotation. The slider switch is a DPDT (double pole; double throw) which reverses the polarity of the drill motor when moved in forward or rearward direction. (See figure 1)

Listing of Phasor™ Drill having Pre-Attached Drill Bits (2 Flute, 15 mm Flute Length)	Final SKU
2 Flute Drill Bit (1.5mm Diameter, 35mm Usable, 75mm Total)	008-1000
2 Flute Drill Bit (2mm Diameter, 35mm Usable, 75mm Total)	008-1001
2 Flute Drill Bit (2.5mm Diameter, 35mm Usable, 75mm Total)	008-1002
2 Flute Drill Bit (2.7mm Diameter, 35mm Usable, 75mm Total)	008-1003
2 Flute Drill Bit (3.2mm Diameter, 35mm Usable, 75mm Total)	008-1004
2 Flute Drill Bit (2mm Diameter, 85mm Usable, 140mm Total)	008-1005
2 Flute Drill Bit (2.5mm Diameter, 85mm Usable, 140mm Total)	008-1006
2 Flute Drill Bit (2.7mm Diameter, 85mm Usable, 140mm Total)	008-1007
2 Flute Drill Bit (3.2mm Diameter, 85mm Usable, 140mm Total)	008-1008
2 Flute Drill Bit (2.5mm Diameter, 140mm Usable, 210mm Total)	008-1009
2 Flute Drill Bit (2.7mm Diameter, 160mm Usable, 210mm Total)	008-1010
2 Flute Drill Bit (3.2mm Diameter, 160mm Usable, 210mm Total)	008-1011
2 Flute Drill Bit (3.2mm Diameter, 85mm Usable, 117mm Total)	008-1028

Listing of Phasor™ Drill having Pre-Attached Drill Bits (2 Flute, Permanent Stop)	Final SKU
2 Flute Drill Bit (1mm Diameter, 6mm Usable, 35mm Total)	008-1020
2 Flute Drill Bit (1mm Diameter, 8mm Usable, 35mm Total)	008-1021
2 Flute Drill Bit (1mm Diameter, 10mm Usable, 35mm Total)	008-1022
2 Flute Drill Bit (1mm Diameter, 12mm Usable, 35mm Total)	008-1023
2 Flute Drill Bit (1mm Diameter, 6mm Usable, 75mm Total)	008-1024
2 Flute Drill Bit (1mm Diameter, 8mm Usable, 75mm Total)	008-1025
2 Flute Drill Bit (1mm Diameter, 10mm Usable, 75mm Total)	008-1026
2 Flute Drill Bit (1mm Diameter, 12mm Usable, 75mm Total)	008-1027

Listing of Phasor™ Drill having Pre-Attached Drill Bits (3 Flute, 15 mm Flute Length)	Final SKU
3 Flute Drill Bit(1.5mm Diameter,35mm Usable,75mm total)	008-1029

3 Flute Drill Bit(2mm Diameter,35mm Usable,75mm total)	008-1030
3 Flute Drill Bit(2.5mm Diameter,35mm Usable,75mm total)	008-1031
3 Flute Drill Bit(2.7mm Diameter,35mm Usable,75mm total)	008-1032
3 Flute Drill Bit(3.2mm Diameter,35mm Usable,75mm total)	008-1033
3 Flute Drill Bit(2mm Diameter,85mm Usable,140mm total)	008-1034
3 Flute Drill Bit(2.5mm Diameter,85mm Usable,140mm total)	008-1035
3 Flute Drill Bit(2.7mm Diameter,85mm Usable,140mm total)	008-1036
3 Flute Drill Bit(3.2mm Diameter,85mm Usable,140mm total)	008-1037
3 Flute Drill Bit(2.5mm Diameter,140mm Usable,210mm total)	008-1038
3 Flute Drill Bit(2.7mm Diameter,160mm Usable,210mm total)	008-1039
3 Flute Drill Bit(3.2mm Diameter,160mm Usable,210mm total)	008-1040

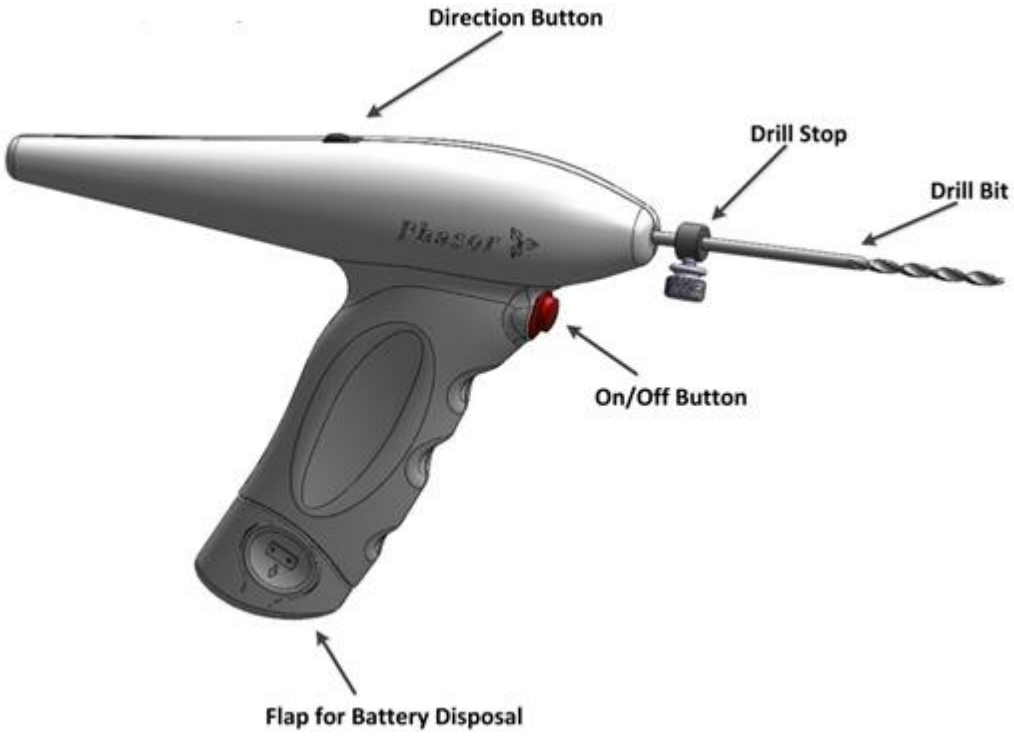

Figure 1

Biocompatibility Testing

Biocompatibility testing for was performed according to ISO 10993-17:2002 and ISO 10993-18:2005 on both the drill bits and the thumbscrew drill stop. In reference to 440A Stainless Steel, bone drill, manufactured under standard ASTM F899, no further biocompatibility testing is necessary due to the known biocompatibility with human tissue and fluids. Complete biocompatibility testing has also been completed by the plastics supplier of the thumbscrew drill

stop, see Appendix F. It is the opinion of Biotex, Inc. that we have meet the necessary biocompatibility requirements for the intended use of the device.

Performance Testing - Bench
Results from the performance testing are provided. The laboratory performance testing was conducted to verify suitability of the design characteristics of the device. The testing consisted of the following: Compression Test, Torque, and Drill Stop (Pull). Results of the testing confirmed the Phasor™ meets design requirements, see Appendix C.

Performance Testing - Animal
No animal testing was performed.

Performance Testing- Distribution/Aging Packaging Integrity
Distribution Challenge Testing and Accelerated Aging Studies were completed to ensure that product integrity is maintained for the intended use. All testing performed was conformal. Product successfully passed the equivalent of one year of aging.

The following are the utilized guidance documents.

- **ASTM F1980-07 (Reapproved 2011), standard guide for accelerated aging of sterile barrier systems for medical devices**
- **ASTM D4169-14, standard practice for performance testing of shipping containers and systems**
- **ASTM F88/F88M-09, standard test method for seal strength of flexible barrier materials**
- **ASTM F2096-11, standard test method for detecting gross leaks in packaging by internal pressurization.**

Accelerating aging data to support a one year shelf life is provided as Appendix D. Also provided in Appendix I is the real time aging protocol which will be used to support a one year and three year shelf life.

Substantial Equivalence
A comparison of the Phasor™ Drill to the predicate devices is provided below. Like the predicate devices, the Phasor Drill is intended to drill through skull bone. The predicate, MicroAire® 1000E System (K014060), does not come sterile however, it is indicated to be sterilized by means of an autoclave. Like the predicated, Sterile Drill Bits (K962913) and the Phasor Drill are supplied sterile and for single use.

Differences in the intended use between the Phasor Drill and the predicate, MicroAire® 1000E System, are that the Phasor Drill **does not** integrate any cutting, sawing, decorticating, shaping, or manipulating of bone and/or bone related tissue. The Indication For Use of The Phasor™ Drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone. The Indication For Use of the proposed device differs from the predicate in no new or different type of safety- or effectiveness-related matter.

The Phasor Drill has some differences in technology than the predicate device. The Phasor Drill is powered by 6 CR cell batteries which generate 18 volts of energy. The use of a hand-held battery-powered device provides clinicians with greater control of angle and freedom of mobility than the predicate MicroAire® 1000E System, which is a tethered, electrically-powered drill. The predicate device MicroAire® 1000E System is powered by electricity to energize the motor and spin the drill bit in order to make a hole in the skull of a patient. Although the technology of the proposed device differs from the predicate, it does not raise any new or different types of safety or effectiveness questions.

The predicate drill bits produced by Synthes, Inc. and the Biotex drill bits are made from surgical grade stainless steel and tooled with 2 and 3 channels. The only differences between the drill bits are the sizes which are offered for sale to consumers (please see table below). The Synthes, Inc. drill bits range in size larger than the drill bits produced by Biotex. There is no significant difference in the Indications For Use; due to the age of the Synthes clearance, additional regulatory language has been added to the Biotex Indication For Use statement. As mentioned previously, a difference exists only in the size of the drill bits offered but does not raise any new or different type of safety or effectiveness questions.

The available performance data demonstrates that the Phasor Drill is safe and performs effectively in achieving a drilled hole in the skull. The Phasor Drill, therefore, is substantially equivalent to the other devices regulated under 21 CFR 882.4310 and 21 CFR 878.4820.

Predicate Device Comparison Table

Device Name	Phasor™ Drill	MicroAire® 1000E System (Predicate Device)	Synthes Sterile Drill Bits (Predicate Device)
510k Number		K014060	K962913
Intended Use	The Phasor™ Drill is as a sterile, single-use, disposable device intended for use on an adult patient during surgical procedures to bore a hole into the skull for insertion of a screw, wire, cable, plate, pin bolt, etc. The applications include cranial and maxillofacial (including neurosurgical) procedures. This device is MRI-Unsafe.	The MicroAire® 1000E System is intended for use in surgical procedures requiring the need for cutting, sawing, drilling, reaming, wire driving, pinning, screw driving, decorticating, shaping and manipulation of bone and related tissue. The applications include ENT, maxillofacial, neurological, oral, orthopedic, plastic, pediatric, and spinal surgery.	Synthes Sterile Drill Bits are intended to bore a hole into bone for insertion of a screw, wire, cable, plate, pin, bolt, etc.
Sterility	Provided sterile for single use.	Provided non-sterile, autoclave-sterilizable	Provided sterile for single use
Single Use	Yes	No	Yes
Device Classification	21 CFR 882.4310	21 CFR 882.4310	21 CFR 878.4820
Drill Bit Diameter	1- 3.2mm	N/A	0.5-2.0mm (for very small bones); 2.1-4.5mm (for small bones); 4.6-13.0mm (for large bones)
Drill Bit Length	Up to 210 mm (measured from drill housing to drill tip)	Not offered	Up to 233 mm
Number of flutes	2 or 3	N/A	2 or 3
Drill Bit Material	Stainless Steel	N/A	Stainless Steel
Drill Bit Removable from Device?	No	Yes	Not Applicable
Power Source	Battery powered (electrical)	Electrical	Not Applicable
Method of Sterilization	Gamma	Autoclave (Provided Non-Sterile)	Gamma
MR Compatibility	No	No	No