DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 19, 2017

OsteoMed
Kathryn Jayne
Senior Specialist, Regulatory Affairs
3885 Arapaho Road
Addison, TX 75001

Re: K162542
Trade/Device Name: OsteoMed Pinnacle Driver
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: February 14, 2017
Received: April 18, 2017

Dear Kathryn Jayne:

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,

Michael J. Hoffmann -S

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)*
K162542

Device Name
PINNACLE Driver

Indications for Use *(Describe)*
The PINNACLE Driver is intended for driving screws and for drilling into bone, in conjunction with cranial surgical 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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510(k) SUMMARY

I. SUBMITTER

OsteoMed
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Contact Person: Kathryn A. Jayne
Date Prepared: May 12, 2017

II. DEVICE

Name of the Device: PINNACLE Driver
Common or Usual Name: Battery-operated drill/driver
Classification Name: Drill, Bone, Powered
Regulation: 882.4310
Regulatory Class: II
Product Code: HBE
Classification Panel: Neurology

III. PREDICATE DEVICE

The OsteoMed "B" Power System, K933101, is the primary predicate. The OsteoMed OsteoPower System, K971692, is the reference predicate.

IV. DEVICE DESCRIPTION

The PINNACLE Driver is a handheld, cordless, software driven, battery operated driver for high speed insertion of screws and drilling of pilot holes. The device operates in both the forward and reverse directions. A sterile, single use battery powers the device and is intended for use solely with the PINNACLE Driver. Accessories for the PINNACLE Driver include hex shank drill bits and driver stems. The optional driver stems are reusable while the drill bits are single use. The PINNACLE Driver may be sterilized in a sterilization tray and/or rigid sterilization container, both of which are available from OsteoMed.

The PINNACLE Driver is intended for use in a healthcare facility/hospital for use by a clinician. The PINNACLE is a prescription device.

The PINNACLE Driver and lithium battery is made of medical grade stainless steel, aluminum, silicone, PEEK, gold plated brass, and medical plastic. The driver stems and drill bits are made of medical grade stainless steel. The sterilization trays and rigid sterilization containers are made of aluminum.

The PINNACLE Driver is a battery operated driver/drill that operates in both the forward and reverse directions. The PINNACLE Driver contains torque limiting software to prevent over-torquing and stripping of screws in drive mode.

V. INDICATIONS FOR USE

The PINNACLE Driver is intended for driving screws and for drilling into bone, in conjunction with cranial surgical procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following same technological elements as demonstrated below.

	Subject Device—OsteoMed PINNACLE Driver & Accessories	Primary Predicate—OsteoMed "B" Power System & Accessories	Reference Predicate—OsteoMed OsteoPower System & Accessories
510(k)	Pending	K933101	K971692
Regulation No.	882.4310	872.4120	872.4120
Product Code	HBE	KIJ	KMW
Device Class	II	Unclassified	II
Regulatory Panel	Neurology	Dental	Dental
Indications for Use	The PINNACLE Driver is intended for driving screws and for drilling into bone, in conjunction with cranial surgical procedures.	The OsteoMed "B" Power Handpiece System is intended for drilling and cutting bone and teeth and for driving pins, screws, and/or wires into bone for dental, craniofacial, orthognathic, mandibular, hand, foot, wrist, or extremity reconstruction surgical procedures.	The OsteoPower System and Accessories are indicated for drilling or cutting bone or teeth, and for driving screws and/or pins and wires into bone, in conjunction with dental, craniofacial, craniotomies, orthognathic, spinal, mandibular, hand, foot, wrist, and extremity reconstruction surgical procedures.
Power Source	Battery operated (Lithium, single patient use)	Battery operated (rechargeable NiCad battery)	AC/DC External power supply
Material	--Handpiece and battery—Aluminum, PEEK, brass, medical grade stainless steel, silicone	--Handpiece and battery—stainless steel, aluminum, brass, silver, medical grade plastics, fiber reinforced ceramics	--Handpiece only—stainless steel or carbide --Cutting portion of the drills or burrs—stainless steel, carbide, diamond, or fiber reinforced ceramic

	Subject Device—OsteoMed PINNACLE Driver & Accessories	Primary Predicate—OsteoMed "B" Power System & Accessories	Reference Predicate—OsteoMed OsteoPower System & Accessories
	--accessories—medical grade stainless steel, aluminum	--accessories—medical grade stainless steel or carbide	--Accessories—stainless steel, aluminum, or medical grade plastics
Speed	2,000 RPM forward 275 RPM reverse	120-1800 RPM	608-70,000 RPM
Battery	Disposable, lithium, single use, sterile battery (gamma)	Rechargeable Nickel Cadmium battery	NA
Modes	Drill Drive	Drill Drive	Speed ranges SAFETY, 100%, 75%, 50%, 25%, and Di (12.5%) of maximum speed
Activation Buttons	1 Forward button 1 Reverse button	1 Forward button 1 Reverse button	1 Forward button 1 Reverse button
Insertion Material	Bone	Bone	Bone
Screw sizes/insertion	1.2mm, 1.6mm, 2.0mm	1.6mm, 2.0mm	1.2mm, 1.6mm, 2.0mm
Collet	Pull-back collet	Pull-back collet	Twist collet
Accessories	Hex Shank drill bits, Hex Shank driver stems, sterilization trays, rigid sterilization container	Round burrs, oval burrs, twist drills, wire pass twist drills, side cutting burs, and end-cutting drills, saw blades, K-wires and pins, screw drivers, burr racks, blade containers, sterilization trays, battery charger	Round burrs, oval burrs, twist drills, wire pass twist drills, side cutting burrs, end-cutting drills, saws, motor units, modules, footswitches, screw drivers
Sterilization of re-usable devices	Pre-vacuum steam (wrapped)—Hand piece only --Min. Temp: 132º C (270ºF) --Full Cycle Time: 4 minutes --Min Dry Time: 30 minutes Pre-vacuum steam (rigid container)— 1-Driver Case & 2-Driver Case --Min. Temp: 132º C (270ºF) --Full Cycle Time: 4 minutes --Min Dry Time: 30 minutes	Pre-vacuum Hi Vac (wrapped or unwrapped) Temp: 270-270 ºF Exposure Time: 4 min Dry Time: min 8 min 270 ºF Gravity (wrapped on tray) Temp: 270-270 ºF Exposure Time: 35 min Dry Time: min 8 min	Pre-vacuum steam (wrapped) Temp: 132º C (270ºF) Dwell Time: 10 minutes Dry Time: 70 minutes

	Subject Device—OsteoMed PINNACLE Driver & Accessories	Primary Predicate—OsteoMed "B" Power System & Accessories	Reference Predicate—OsteoMed OsteoPower System & Accessories
Parameter Control Technology	Software	Non-programmable, discrete digital and analog logic	Non-programmable, discrete digital and analog logic
Software/safety features	-Senses torque to prevent over-torquing & stripping of screws	NA	Motor unit control switch to temporarily disable the Electric Drive

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the device was conducted in accordance with the FDA Blue Book Memorandum #G95-1.

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Subchronic toxicity
- Genotoxicity
- Implantation
- Pyrogen testing

The device and associated accessories are considered tissue/bone/dentin contacting for a duration of less than 24 hours. However, OsteoMed conducted a biocompatibility evaluation of the exposed material of the driver as worst case, based on an implant device due to the close proximity to the patient. The sterilization trays and rigid containers are considered non-patient contacting.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The system complies with the IEC 60601-1 and IEC 60086-4 standards for safety and the ES60601-1 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices." The software for this device was considered as "minor" level of concern as documented in this submission.

Bench Testing

The following bench testing was conducted:

- Simulated Use/Design Verification Testing (DVT)
- Sterilization Validation
- Reprocessing Validation
- Shipping Validation
- Battery Safety Testing
- Electrical Safety and Electromagnetic Compatibility

Animal Study

No animal studies were needed to demonstrate substantial equivalence to the declared predicate.

Clinical Studies

No clinical studies were needed to demonstrate substantial equivalence to the declared predicate.

Testing Summary

Test	Test Method Summary	Results
Design Verification Testing (DVT)	Conducted on subject devices with software and powered by single use batteries. The driver was switched to drill mode and a drill bit was used to drill a pilot hole. The mode was switched back to drive mode and a driver stem was used to fully seat a specified screw. Still in drive mode, the driver was used to remove screws.	The cycle was repeated 99 times and the subject device performed as intended after the 99 cycles.
Screw Characterization	Released screws of various length and diameter were used with the subject device. A torque analyzer was used to retrieve the data after the screw was seated or stripping noted. Torque and seat value was then calculated.	The data collected was used as an input into the torque limiting software.
Sterilization Validation	Sterilization validation was conducted on subject devices per using overkill sterilization method validating an SAL of 10^{-6} per AAMI TIR12:2010. The validation was conducted using the sterilization parameters defined in IFU. The validation was conducted on individually wrapped drivers and the driver and accessories placed inside an organizational tray inside a rigid container.	Having met the predetermined acceptance criteria, the method outlined on the IFU was validated as an effective means of sterilizing the subject device.
Reprocessing (Cleaning) Validation	Automatic Cleaning Conducted on subject devices in worst case configuration based on FDA Guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued March 17, 2015. Worst case cleaning processing (minimum durations for the cleaning steps as defined in the IFU). Acceptance criteria was based on AAMI TIR 30.	Automatic cleaning was validated as an effective means of cleaning the subject device.

Test	Test Method Summary	Results
Packaging & Shipping Validation	Shipping validation was conducted on subject devices using ASTM D4169 after environmental conditioning per ASTM D4332-14.	The packaging fully contained and protected the device from exposure to normal shipping hazards and the device functioned as intended after shipment.
Battery Safety Testing	Conducted on subject devices per IEC 60086-4 (ed.3) and Sixth Revised Edition of Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.	The subject devices comply with requirements in the applicable standards.
Biocompatibility	The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1.	The subject devices are considered non-toxic and biocompatible.
Electrical Safety and EMC Testing	Conducted on subject device per IEC 60601-1, IEC 60086-4, and ES60601-1	Subject device complies with requirements in the applicable standards.

VIII. CONCLUSIONS

The basis of substantial equivalence for the device is based on similarities in indications for use, material, function, performance, design, technology, sterilizations, and operating principles. The non-clinical data support the substantial equivalence of the device and the verification and validation demonstrate that the device should perform as intended in the specified use conditions.

(End of Summary)