



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

June 23, 2015

Synthes (USA) Products, LLC
Ms. Susan Lewandowski
Project Leader, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K150796
Trade/Device Name: Dental Bone Cutting Instruments
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZJ
Dated: March 25, 2015
Received: March 26, 2015

Dear Ms. Lewandowski:

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,

 Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150796

Device Name

Dental Bone Cutting Instruments

Indications for Use (Describe)

The Dental Bone Cutting Instruments are nonpowered hand-held devices intended for trauma, reconstruction, or orthognathic procedures to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw.

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

Date Prepared: June 23, 2015

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United States of America

Contact: Susan Lewandowski
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DEVICE

Device Name: Dental Bone Cutting Instruments
Classification Name: Bone cutting instruments and accessories
Regulatory Class: II
Product code: DZJ (Driver, Wire, and Bone Drill Manual)
21 CFR 872.4120

PREDICATE DEVICE

Synthes 90° Screwdriver K082649 is the primary predicate.

Medtronic Sofamor Danek POWEREASE System K123270 is used as a reference device in support of this submission.

DEVICE DESCRIPTION

Dental bone cutting instruments are taps and countersinks. Countersinks are used to create a countersink feature in bone to provide a contact surface for screw heads and to reduce the palpability of the screw head. Taps are used to create threads in a pre-drilled hole in order to accommodate a bone screw. The taps and countersinks are manufactured from Stainless Steel 440A in accordance with ASTM F899 Standard Specification for Stainless Steel for Surgical Instruments as well as ASTM A276 Specification for Stainless Steel Bars and Shapes.

INDICATIONS FOR USE

Dental Bone Cutting Instruments

Dental bone cutting instruments are nonpowered hand-held devices intended for trauma, reconstruction, or orthognathic procedures to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw.

Synthes 90° Screwdriver

The Synthes 90° Screwdriver is indicated for the manual and powered pre-drilling and insertion of bone fixation screws in oral/maxillofacial surgery.

Both the dental bone cutting instruments and the primary predicate Synthes 90° Screwdriver K082649 are indicated for use in oral/maxillofacial surgery to drill or cut into the upper or lower jaw; both have product code DZJ. Additionally, the dental bone cutting instruments defined herein as Class II product code DZJ are the same instruments currently marketed by Synthes as Class I product code LXH (Orthopedic manual surgical instruments). The same instruments have two intended uses.

The reference device Medtronic Sofamor Danek POWEREASE System K123270 does not have the same intended use as the dental bone cutting instruments as the POWEREASE system is used during spinal surgery. The reference system is intended for “drilling, tapping and driving screws” and includes instruments such as taps, drill bits, screwdrivers, etc. The product code is HBE (Drills, Burrs, Trephines and Accessories – simple, powered). The reference device is included to show that taps have been cleared within premarket notification submissions.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Primary Predicate

Both the dental bone cutting instruments and the primary predicate Synthes 90° Screwdriver K082649 are indicated for use in oral/maxillofacial surgery to drill or cut into the upper or lower jaw. Additionally, the dental bone cutting instruments defined herein as Class II product code DZJ are the same instruments currently marketed by Synthes as Class I product code LXH. The same instruments have two intended uses.

Technological Similarities of Dental Bone Cutting Instruments to Primary Predicate

- Both instruments are intended to be used for predrilling a hole in preparation for a bone screw to be placed in the upper or lower jaw
- Both can be operated manually
- Both are manufactured from stainless steel

Technological Differences of Dental Bone Cutting Instruments to Primary Predicate

- The 90° Screwdriver is used to drive or insert screws as well as to cut bone; the tap is only used to cut threads into bone to receive a bone screw and the countersink is only used to create a countersink feature in bone to reduce palpability of the screw head
- The 90° Screwdriver can be operated manually or with power; the dental bone cutting instruments are manual instruments only

Reference Device

Both the dental bone cutting instruments and the reference device Medtronic Sofamor Danek POWEREASE System K123270 are generally intended to be used during surgery for the cutting into bone. The reference device is included to show that taps have been cleared within premarket notification submissions.

Technological Similarities of Dental Bone Cutting Instruments to Reference Device

- Both devices are intended to be used to prepare bone for placement of a screw

- Taps from the POWEREASE system can be operated manually like the dental bone cutting instruments
- Both are manufactured from stainless steel

Technological Differences of Dental Bone Cutting Instruments to Reference Device

- The POWEREASE System instruments are intended for drilling, tapping and driving screws; the dental bone cutting instruments have a more limited intended use - the tap is only used to cut threads into bone to receive a bone screw and the countersink is only used to create a countersink feature in bone to reduce palpability of the screw head
- The POWEREASE System instruments can be operated manually or with power; the dental bone cutting instruments are manual use only
- The POWEREASE System is intended for spinal surgery (Neurology), the Dental Bone Cutting instruments are intended for oral/maxillofacial surgery (Dental)

SE Summary

There are technological differences between the subject device and both the predicate and reference devices. However, the technological differences do not raise different questions of safety and effectiveness, and are related to the more limited intended use and simpler operating principle of the subject device as compared to the two previously cleared devices.

PERFORMANCE DATA

Mechanical Testing

The performance data provided in support of substantial equivalence of the proposed devices are as follows:

- Tolerance Analysis
- Torque and Torsional Testing
- Reliability Analysis

Clinical Studies

Clinical testing was not necessary for the determination of substantial equivalence.

The performance data demonstrate that the mechanical performance of the proposed dental bone cutting instruments e.g. taps and countersinks is comparable to that of the primary predicate device and supports substantial equivalence to the primary predicate device for safe and effective bone cutting in the upper and lower jaw.



CONCLUSIONS

The proposed devices have the same intended use as the primary predicate device. The mechanical testing included in this submission demonstrates that:

- Any differences in technological characteristics of the primary predicate and/or reference device do not raise any new questions of safety and effectiveness.
- The proposed devices are at least as safe and effective as the primary predicate.

It is concluded that the information included in this submission supports substantial equivalence.

Device Comparison Table

	DePuy Synthes Dental Bone Cutting Instruments, e.g. Taps and Countersinks (subject devices)	DePuy Synthes Bone Cutting Instruments (Class I equivalents – Product Code LXH)	Synthes 90° Screwdriver K082649 (primary predicate)	Medtronic Sofamor Danek POWEREASE System K123270 (reference device)
Indications for use	The Dental Bone Cutting Instruments are nonpowered hand-held devices intended for trauma, reconstruction, or orthognathic procedures to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw.	An orthopedic manual surgical instrument is a nonpowered hand-held device intended for medical purposes to manipulate tissue or for use with other devices in orthopedic surgery.	The Synthes 90° Screwdriver is indicated for the manual and powered pre-drilling and insertion of bone fixation screws in oral/maxillofacial surgery.	The IPC System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures. The IPC POWEREASE System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in the placement or cutting of screws, posts and rods.
FDA Product Code	DZJ	LXH	DZI, DZJ	HBE, HWE, GWF
21 CFR	872.4120	888.4540	872.4120	882.4310
Regulation Description	Bone cutting instrument and accessories	Orthopedic manual surgical instruments	Bone cutting instrument and accessories	Powered simple cranial drills, burs, trephines, and their accessories
Review Panel	Dental	Orthopedic	Dental	Neurology
Device Class	2	1	2	2

	DePuy Synthes Dental Bone Cutting Instruments, e.g. Taps and Countersinks (subject devices)	DePuy Synthes Bone Cutting Instruments (Class I equivalents – Product Code LXH)	Synthes 90° Screwdriver K082649 (primary predicate)	Medtronic Sofamor Danek POWEREASE System K123270 (reference device)
Device Description	<p>Countersinks are intended to create a countersink feature in bone to provide a contact surface for screw heads and to reduce palpability of the bone screw.</p> <p>Taps are intended to create threads in a pre-drilled hole in order to accommodate a bone screw.</p>	<p>Countersinks are intended to create a countersink feature in bone to provide a contact surface for screw heads and to reduce palpability of the screw.</p> <p>Taps are intended to create threads in a pre-drilled hole in order to accommodate a bone screw.</p>	<p>The Synthes 90° Screwdriver consists of a screwdriver handle, shaft, screw holder, screw holder insert and a variety of attachments such as drill bits and screwdriver blades for manual and powered right angled pre-drilling and insertion of screws.</p> <p>The screw holder can be turned at an angle behind the screwdriver head for improved visibility.</p>	<p>The POWEREASE™ System Working Ends consists of instruments such as taps, drill bits, screwdrivers, post cutter, set screw break-off tool, reduction nut driver and sleeves. The working ends have a manual alternative. The working ends, listed above, are compatible with the CD HORIZON SOLERA and the TSRH 3Dx Spinal System implants. Of the working ends, only the taps, screwdrivers, drill bits, and sleeves are also compatible with Medtronic's NIM-ECLIPSE Spinal System.</p>
Device material(s)	Stainless steel 440A	Stainless steel	Stainless Steel, Aluminum	Stainless Steel
Principles of function/technology	Countersinks feature cutting flutes at the working end of the instrument that continue a distance up the shaft of the instrument and a centering pin at the working end of the instrument. The user will insert the centering pin into a drilled pilot hole, ensuring	Countersinks feature cutting flutes at the working end of the instrument that continue a distance up the shaft of the instrument and a centering pin at the working end of the instrument. The user will insert the centering pin into a drilled pilot hole, ensuring	<p>The 90° Screwdriver is designed to transmit the torque required for screw insertion.</p> <p>The low profile head provide minimal overall height for minimally invasive pre-drilling and insertion of</p>	The instrument modifications detailed in this submission have no impact on the technological characteristic of the existing instruments. The working end Taps are intended for tapping during spinal surgery, including both open and minimally invasive

	DePuy Synthes Dental Bone Cutting Instruments, e.g. Taps and Countersinks (subject devices)	DePuy Synthes Bone Cutting Instruments (Class I equivalents – Product Code LXH)	Synthes 90° Screwdriver K082649 (primary predicate)	Medtronic Sofamor Danek POWEREASE System K123270 (reference device)
	<p>that the countersink feature is concentric with the drilled hole.</p> <p>Taps are designed to be compatible with corresponding Synthes screws and/or drill bits Taps have cutting threads that run along the length of the instrument. The diameter and thread profile of the tap is designed to match to the diameter and thread profile of an associated screw</p>	<p>that the countersink feature is concentric with the drilled hole.</p> <p>Taps are designed to be compatible with corresponding Synthes screws and/or drill bits Taps have cutting threads that run along the length of the instrument. The diameter and thread profile of the tap is designed to match to the diameter and thread profile of an associated screw</p>	<p>screws in the mandible.</p> <p>The instrument can be attached to a power source for drilling; maximum input speed in 15,000 rpm. The screw holder can be turned at an angle behind the screwdriver head for improved visibility, simple handling and minimally invasive use at the surgical site.</p> <p>The instrument is suitable for right-angled pre-drilling of holes for screw insertion.</p>	<p>procedures. The working ends are used to facilitate the placement of the rods. Like the predicate POWEREASE System instruments, the subject instruments are manufactured from stainless steel.</p>

(End of summary)

