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

January 18, 2017

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

Re: K153587
Trade/Device Name: Taps for Resorbable Screws
Regulation Number: 21 CFR 882.4300
Regulation Name: Manual Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: HBG
Dated: December 22, 2016
Received: December 23, 2016

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,

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)*
K153587

Device Name
Taps for Resorbable Screws

Indications for Use *(Describe)*
Taps are nonpowered hand-held devices intended for bone cutting and drilling on a patient's skull during fracture repair and reconstructive procedures of the cranium.
The taps may be used to prepare cranial bone to insert bone fixation screws.

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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SYNTHES®

510(k) Summary

Date Prepared: January 18, 2017

Submitter: Synthes USA Products, LLC
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Contact: Susan Lewandowski
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DEVICE

Device Name:	Taps for Resorbable Screws
Classification Name:	Drills, burrs, trephines, and accessories (Manual)
Review Panel:	Neurology
Regulatory Class:	II
Product Code:	HBG (Manual cranial drills, burrs, trephines, and their accessories) 21 CFR 882.4300

PREDICATE DEVICE

Medtronic Sofamor Danek POWEREASE™ System K123270 is the primary predicate.

Synthes Dental Bone Cutting Instruments K150796 is used as a reference device in support of this submission.

DEVICE DESCRIPTION

Taps are used to drill a hole and simultaneously create threads in order to accommodate a Rapid Resorbable Fixation System bone screw. The self-drilling fixed-stop taps are manufactured from Stainless Steel 440A which conforms to ASTM F899 Standard Specification for Stainless Steel for Surgical Instruments and ASTM A276 Specification for Stainless Steel Bars and Shapes. The adjustable-length taps (final assembly) are assembled from three components; the adjustable tap (Stainless Steel 440A), the locking collar (Makrolon Rx2530 W/1118 Tint), and the stop collar (Stainless Steel 316L with an aluminum titanium nitride coating).

DePuy Synthes Taps for Resorbable Screws can be used with the following handles:
311.01.98 Handle, with mini quick coupling
311.03 Handle, with mini quick coupling, small
311.005 Screwdriver Handle with hex coupling, small
311.006 Screwdriver Handle with hex coupling, medium
311.007 Screwdriver Handle with hex coupling, large

The DePuy Synthes Taps for Resorbable Screws can be used with the DePuy Synthes Rapidsorb® Rapid Resorbable Fixation System (K062789) screws [1.5mm, 2.0mm, 2.5mm (Emergency) diameters] and plates (1.5 mm and 2.0mm).

INDICATIONS FOR USE

Taps for Resorbable Screws

Taps are nonpowered hand-held devices intended for bone cutting and drilling on a patient's skull during fracture repair and reconstructive procedures of the cranium. The taps may be used to prepare cranial bone to insert bone fixation screws.

Medtronic Sofamor Danak POWEREASE System (Primary Predicate)

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 placement or cutting of screws, posts and rods.

Discussion

Both the subject taps and the primary predicate Medtronic Sofamor Danek POWEREASE System K123270 are intended for use in neurosurgical procedures to drill or cut into the skull. There is a difference in the assigned FDA product codes:

- The subject taps are manual instruments, with a corresponding product code of HBG (Drills, burrs, trephines, and their accessories – manual).
- The primary predicate is a powered instrument with the corresponding product code of HBE (drills, burrs, trephines, and accessories – simple, powered).

Additionally, the subject taps defined herein as Class II product code HBG are the same instruments currently marketed by Synthes as Class I product code LXH (Orthopedic manual surgical instruments). Thus, the subject taps include the intended uses of both product codes (i.e. cranial bone-cutting and general orthopedic bone cutting).

The reference device Synthes Dental Bone Cutting Instruments K150796 does not have the same intended use as the subject taps since the dental bone cutting instruments are intended for trauma, reconstruction, or orthognathic procedures to drill or cut into the upper or lower jaw. The reference device product code is DZJ (Driver, wire, and Bone Drill Manual). Since taps for general orthopedic bone-cutting would typically be considered Class I Exempt instruments, the identified reference device is included to show that taps have been previously cleared within premarket notification submissions.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Primary Predicate

DePuy Synthes considers the subject taps equivalent to the Medtronic Sofamor Danek Sofamor Danek POWEREASE™ System K123270, as well as the Synthes Dental Bone Cutting Instruments K150796.

Technological Similarities of Taps to the Primary Predicate

- Both instruments are used for drilling a hole in preparation for a bone screw
- Both are used in the skull
- Both can be used manually
- The Medtronic POWEREASE™ System consists of a hand piece and attachments; the subject taps consist of the instruments and handles based on the coupling

Technological Differences of Taps to Primary Predicate

- The Medtronic POWEREASE™ System is used for drilling, tapping and driving screws as well as for the placement or cutting of screws, posts and rods; the tap is used to drill a hole and simultaneously create threads in order to receive a bone screw
- The Medtronic POWEREASE™ System can be used manually or with power; the subject taps are manual instruments only
- The Medtronic IPC® and POWEREASE™ Systems (K123270) are used in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures; the subject taps are intended for neurosurgical procedures only

Impact on Safety and Effectiveness

There is no impact to safety and effectiveness. The subject devices have a limited intended use compared to the predicate device; the POWEREASE System is used for drilling, tapping, and driving screws while the taps are used to cut bone in preparation of receiving a bone screw. The subject devices are basic handheld instruments compared to the predicate; the tap is connected to a handle (dependent on the coupling feature) while the predicate device consists of a handpiece and multiple attachments. The subject devices are used manually while the predicate can be used either manually or with power.

Reference Device

Both the subject taps and the reference Dental Bone Cutting Instruments (K150796) are generally intended to be used during surgery for cutting into bone. The reference device is included to show that taps have been cleared within premarket submissions.

Technological Similarities of Taps to the Reference Device

- Both devices are intended to be used to prepare bone for placement of a screw
- Both devices are operated manually
- Both are manufactured from stainless steel (440A)

Technological Differences of Taps to the Reference Device

- The subject taps are intended for use in fracture repair and reconstructive procedures of the cranium (covered under a Neurology product code); the Dental Bone Cutting Instruments are intended for use in oral/maxillofacial surgery (covered under a Dental product code).

Impact on Safety and Effectiveness
There is no impact to safety and effectiveness. The subject taps are intended for use in fracture repair and reconstructive procedures of the cranium (Neurology); the Dental Bone Cutting Instruments are intended for use in oral/maxillofacial surgery (Dental). Regardless of specific intended use, all taps are used to cut bone in preparation of receiving a bone screw. The reference device was included to provide evidence that taps have been cleared within premarket notification submissions.

PERFORMANCE DATA

Mechanical Testing

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

- Simulated Use/Bioskills Lab
- Sawbones Lab
- Torsional Testing of RapidSorb Taps
- RapidSorb Self-Drilling Tap Axial Load at Strip Out
- Validation of Hex Coupling for RapidSorb Adjustable Taps
- Biocompatibility Testing - Cytotoxicity

Performance Testing - Bench		
Test	**Test Method Summary**	**Results**
Simulated Use/Bioskills Lab – RapidSorb Instruments	A representative range of the subject devices will be selected to represent the entire range of taps. The lab will be conducted to validate various aspects of the device design such as torque resistance, length and screw size diameter. The validation lab will consist of 5 individual participants. There will be 4 cadaveric cephalises. The heads (cephalises) will be selected to represent a range of patients (a young male and female, and elderly male and female). The users are independent from the design of the subject device.	The results indicated full validation of the subject device. All acceptance criteria were met.
Saw Bones Lab – Rapidsorb Instruments	The objective of the lab is to validate that the subject taps are able to self-drill in normal density bone. A representative range of the subject device will be selected to represent the entire range of taps. The range includes all diameters and the longest length of each tap. These represent worst case in regard to torque resistance.	The acceptance criteria was met in that all four users were able to use each of the three subject taps to create three separate tapped holes that will accommodate the corresponding screw (36 total insertions).

Performance Testing - Bench		
Test	**Test Method Summary**	**Results**
Mechanical Test – Torsional Testing of RapidSorb Taps	The objective of this test is to demonstrate that the failure torque of RapidSorb self-drilling taps is above the torque at which the same diameter taps will bottom-out in the testing substrate. Two separate tests will be performed, Failure Torque Test and Stripping Torque Test.	The results of this testing indicate that when the failure torque of all three sizes of RapidSorb Self Drilling Taps (1.5, 2.0, and 2.5 mm) are compared to their respective bottoming or stripping torque, the resulting p-values were all 0.000. There is sufficient evidence to reject the null hypothesis in favor of the alternate, that in all cases the RapidSorb failure torque is superior to the Bottoming or Stripping torque (as specified). This satisfies the acceptance criteria.
Mechanical Test – RapidSorb Self-Drilling Tap Axial Load at Strip Out	The objective of this test was to demonstrate that the axial force required to cause the adjustable stop on the adjustable length taps (311.100, 311.101, 311.102, 311.110, 311.111, 311.112) to unintentionally move is greater than the axial force that is generated by the strip out torque of each tap.	As can be seen in all comparisons (1.5, 2.0, and 2.5mm) the resulting p-value was 0.000, which is sufficient evidence to reject the null hypothesis in favor of the alternate that the Axial load required to move the adjustable stop was superior to the axial load at strip-out in all cases. This result satisfies the acceptance criteria.
Validation of Hex Coupling for RapidSorb Adjustable Taps	The objective of this test was to validate the compatibility of the Hex coupling on the proximal end of the RapidSorb Adjustable length taps. All tested parts will couple with the designated hex handles and, then be fully inserted into 40 lbs/cf polyurethane foam with no slippage or visible damage (no magnification) of taps proximal coupling.	At the conclusion of the testing, all participants were able to drive all 12 taps with a combination of the 3 specified handles. This was done with no visible damage to the proximal coupling end of the tap.
Biocompatibility (Cytotoxicity)	An *in vitro* study was conducted to evaluate for potential cytotoxic effects, following guidelines of the ANSI/AAMI/ISO 10993-5, Biological Evaluation of medical devices – Part 5: Test for in vitro cytotoxicity (2009).	At the conclusion of the testing, the test articles extract showed no reactivity of causing cell lysis or toxicity. All test method acceptance criteria were met. The patient contacting components of taps are manufactured from Stainless Steel 440A which conforms to the FDA recognized consensus standard, ASTM F899 - Standard Specification for Stainless Steel for Surgical Instruments, supporting the biocompatibility of this device.

Performance testing demonstrates that the mechanical performance of the proposed taps is comparable to that of the primary predicate device (taps) and supports substantial equivalence.

Clinical Studies

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

The performance data demonstrate that the mechanical performance of the proposed taps 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 skull.

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 Taps for Resorbable Screws (subject device)	Medtronic Sofamor Danek POWEREASE System K123270 (primary predicate)	DePuy Synthes Dental Bone Cutting Instruments, e.g. Taps and Countersinks K150796 (reference device)
Indications for use	Taps are nonpowered hand-held devices intended for bone cutting and drilling on a patient's skull during fracture repair and reconstructive procedures of the cranium. The taps may be used to prepare cranial bone to insert bone fixation screws.	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.	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.
FDA Product Code	HBG	HBE, HWE, GWF	DZJ
21 CFR	882.4300	882.4310	872.4120
Regulation Description	Manual cranial drills, burrs, trephines, and their accessories	Powered simple cranial drills, burrs, trephines, and their accessories	Bone cutting instrument and accessories
Review Panel	Neurology	Neurology	Dental
Device Class	2	2	2
Device Description	Taps are used to drill a hole and simultaneously create threads in order to accommodate a Rapid Resorbable Fixation System bone screw. The taps are available as self-drilling fixed-stop taps and self-drilling adjustable-stop taps.	The POWEREASETM 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.	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. Taps are intended to create threads in a pre-drilled hole in order to accomodate a bone screw.
Technological characteristics:			
Principles of function/technology	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	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	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

	DePuy Synthes Taps for Resorbable Screws (subject device)	Medtronic Sofamor Danek POWEREASE System K123270 (primary predicate)	DePuy Synthes Dental Bone Cutting Instruments, e.g. Taps and Countersinks K150796 (reference device)
	thread profile of the tap is designed to match to the diameter and thread profile of an associated screw.	during spinal surgery, including both open and minimally invasive 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.	instrument. The user will insert the centering pin into a drilled pilot hole, ensuring that the countersink feature is concentric with the drilled hole. 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.
Dimensions			
Stop Depth:	Fixed stop taps: 3mm, 4mm, 5mm, 6mm, 8mm Adjustable stop taps: 3-8mm (1mm increments)	Unknown	20-122mm tapping depths
Couplings:	Mini-quick coupling Hex coupling	Unknown	Hex coupling
Compatible Screws:	Rapidsorb resorbable cortex screws: 1.5mm, 2.0mm, 2.5mm diameter	Unknown	Cortex screws: 1.3-3.0mm diameter
Device material(s)	Stainless steel 440A, 316L Polycarbonate (Makrolon Rx2530 W/1118 Tint) Aluminum titanium nitride coating	Stainless Steel	Stainless steel 440A

(End of summary)