K112583 (1/2)

DEC - 5 2011

Attachment 2: Revised 510(k) Summary

Sponsor:	Synthes (USA) Rebecca Blank Associate Regulatory Affairs Specialist 1301 Goshen Parkway West Chester, PA 19380 (610) 719-1268 FAX (484) 356-9682
Date Prepared:	August 31, 2011
Device Name:	Synthes Cortical Screws
Classification:	Class II, § 888.3040 - Smooth or Threaded Metallic Bone Fixation Fastener Product Code: HWC
Predicate Device(s):	K030310 - Synthes Stainless Steel Modular Hand System K010321 - Synthes Modular Foot System – 2.7mm Module K043185 - Synthes 3.5mm Cortex Screws K111230 - Synthes 3.5mm Low Profile Cortical Screws K000684- Small Fragment Dynamic Compression Locking (DCL) System K000682 - Synthes Large Fragment Dynamic Compression Locking (DCL) System K100776 - Synthes 2.4mm/2.7mm Variable Angle LCP Forefoot/Midfoot System K023879-Synthes Small Titanium Wrist Fusion Plate
Device Description:	Screws have self-tapping features, stardrive, hexdrive, or cruciform head recesses, and are manufactured from stainless steel, commercially pure titanium, and/or titanium alloy. Cortex screws are offered both sterile and non sterile and are available in various lengths. Screws may be used independently or with any Synthes plate which accepts 1.0mm, 1.3mm, 2.0mm, 2.4mm, 2.7mm, 3.5mm, 4.0mm, and 4.5mm cortex screws. The subject screws, when used in pediatric applications, may be used independently or with compatible Synthes plates which are also indicated for pediatric populations.
Indications for Use:	The Synthes 1.0mm, 1.3mm, 1.5mm, 2.0mm, and 2.4mm Cortex Screws are intended for use in trauma procedures, reconstructive procedures, and general surgery of the hand, wrist, and other small

bones and bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The Synthes 2.7mm Cortex Screw is intended for fractures and osteotomies of small bones and bone fragments, including the foot, ankle, and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. The Synthes 2.7mm Cortex Screw may also be used in fusion applications in adults and adolescents (12-21years) when used with the Synthes 2.4mm/2.7mm Variable Angle LCP Forefoot/Midfoot System (K100776) and in adults and pediatric patients (2-12 years) when used with the Synthes Ti Wrist Fusion Plate (K023879).

The Synthes 3.5mm and 4.0mm Cortex Screws are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The Synthes 4.5mm Cortex Screw is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of non-unions or malunions in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

Substantial Equivalence:

Information presented supports substantial equivalence of the Synthes Cortex Screws to the predicate devices. The proposed Synthes Cortex Screws have similar indications for use, are similar in design, incorporate the same fundamental product technology and are composed of the same materials. The intent of this 510(k) submission is to expand the indications for use statement to include the use of the device in pediatric patient populations. Published, clinical literature has been provided to support the use of 1.0mm, 1.3mm, 2.0mm, 2.4mm, 2.7mm, 3.5mm, 4.0mm, and 4.5mm Synthes Cortex Screws for the proposed indications and populations, and supports a substantially equivalent decision in comparison to predicate Synthes Cortex Screws.

To additionally support substantial equivalence, calculations comparing torsional strength, insertion torque, axial pullout, and bending strength were performed. Screw length was determined to have no bearing on the cortical screws' performance or technical function, and therefore does not raise any new questions of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 5 2011

Synthes (USA) Products LLC
% Ms. Rebecca Blank
Associate Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K112583
Trade/Device Name: Cortical Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 31, 2011
Received: September 6, 2011

Dear Ms. Blank:

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.

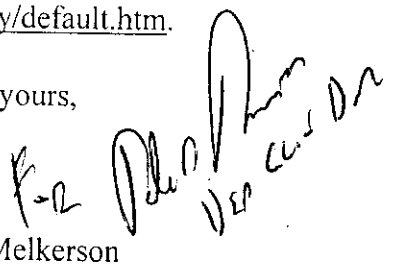
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112583(1/1)

Attachment 1: Revised Indications for Use

510(k) Number (if known): _____

Device Name: Synthes (USA) Cortical Screws

Indications for Use:

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The Synthes 2.7mm Cortex Screw is intended for fractures and osteotomies of small bones and bone fragments, including the foot, ankle, and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. The Synthes 2.7mm Cortex Screw may also be used in fusion applications in adults and adolescents (12-21years) when used with the Synthes 2.4mm/2.7mm Variable Angle LCP Forefoot/Midfoot System (K100776) and in adults and pediatric patients (2-12 years) when used with the Synthes Ti Wrist Fusion Plate (K023879).

The Synthes 3.5mm and 4.0mm Cortex Screws are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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Prescription Use __X__ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112583