K110592(1/2)

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JUL 25 2011

5.0 - 510(k) Summary or 510(k) Statement

Date Prepared:	7/22/2011
Purpose for Submission:	To introduce a new dynamic screw system (3.7mm / 5.0mm Dynamic Locking Screws) into interstate commerce.
Sponsor:	Synthes Christopher Hack, Esq. 1301 Goshen Parkway West Chester, PA 19380 Tel: 610-719-6940 Fax: 484.356.9682
Device Name:	3.7mm / 5.0mm Dynamic Locking Screws
Classification:	Class II 888.3030 – smooth or threaded metallic bone fixation fastener HWC
Predicate Device:	K101696 – Zimmer Motion Loc Screw for NCB Polyaxial Locking Plate System K961413 – Synthes Anatomical Locking Plate System K963192 – Synthes 3.5/4.0mm Cannulated Screws K000682 – Synthes Large Fragment Dynamic Compression Locking System K000684 – Synthes Small Fragment Dynamic Compression Locking System
Device Description:	The 3.7mm / 5.0mm Dynamic Locking Screws are similar to locking screws, but feature a pin-in sleeve design. This design allows for micro movement within the angularly stable system and the screw-plate interface. The motion is contained within the DLS. The DLS are designed to be used with all applicable legally marketed Synthes Locking Compression Plates (LCP).
Intended Use:	Synthes Dynamic Locking Screws (DLS) in combination with Synthes Locking Compression Plates (LCP) are intended for use in long bone fractures, the fixation of osteopenic bone, the fixation of osteotomies, and for the fixation of non-unions and malunions.
Substantial Equivalence:	The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of the subject components to the predicate device in regards to mechanical strength. In addition, the intended use, manufacturing methods, packaging, and sterilization of the predicate and subject components are identical. Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject device: 3.7mm / 5.0mm Dynamic Locking Screws to the predicate devices. Testing conducted to support the substantial equivalence for the 3.7mm /

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5.0mm Dynamic Locking Screws was aimed to assess the fatigue strength of the subject device. The Dynamic Locking Screws were tested evaluated in fatigue, insertion torque, fretting corrosion, and pullout resistance.

Testing using an ovine tibial osteotomy model was conducted to demonstrate lack of adverse effect on bone healing as compared to a predicate device.

The results of the evaluations confirm that the subject device is substantially equivalent to the predicate devices.

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

Synthes
% Mr. Christopher Hack, Esq.
Senior Regulatory Specialist
1301 Goshen Parkway
West Chester, Pennsylvania

JUL 25 2011

Re: K110592
Trade/Device Name: 3.7mm/5.0mm Dynamic Locking Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HWC
Dated: June 22, 2011
Received: June 24, 2011

Dear Mr. Hack:

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.

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,

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

Enclosure

K110592
(1/1)

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Attachment E - Indications for Use Statement

510(k) Number (if known): _____

Device Name: 3.7mm / 5.0mm Dynamic Locking Screws

Indications for Use:

Synthes Dynamic Locking Screws (DLS) in combination with Synthes Locking Compression Plates (LCP) are intended for use in long bone fractures, the fixation of osteopenic bone, the fixation of osteotomies, and for the fixation of non-unions and malunions.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (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)

for M. Melkerson

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

510(k) Number K110592