



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Synergy Surgical Technologies, Inc.
% Paxmed International, LLC
Kevin Thomas
11234 El Camino Real, Suite 200
San Diego, California 92130

OCT - 2 2009

Re: K092082

Trade/Device Name: Synergy Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN°
Dated: July 7, 2009
Received: July 9, 2009

Dear Mr. Thomas:

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.

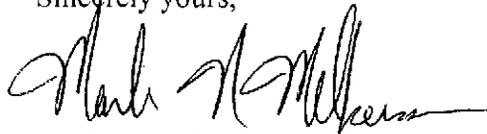
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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" (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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

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

Enclosure

Indications for Use

510(k) Number (if known): K092082 (pg 1/1)

Device Name: Synergy Cannulated Screw System

Indications for Use:

The Synergy Cannulated Screw System is intended for long and small bone fracture fixation, including: fractures of the tarsals and metatarsals; metatarsal and phalangeal osteotomies; fractures of the carpals and metacarpals; carpal and metacarpal arthrodesis; small fragments of the hand and wrist; ligament fixation as appropriate; sacroiliac joint disruptions; fractures of the distal femur and proximal tibia; intracapsular fractures of the hip; ankle arthrodesis; and pelvis and acetabulum fractures. This system is not indicated for use in the spine.

Prescription Use X
(Part 21 CFR 801 Subpart D)

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)

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Jonita J. for mmm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092082

Description

DBX[®] Inject is completely resorbable and is composed of donated cortical and cancellous bone. The bone granules are mixed with sodium hyaluronate (Hy). DBX[®] Inject consists of DBX Putty or Paste with a separate, sterile plastic syringe for delivery directly into the operative site.

Intended Use (Indications)

DBX[®] Inject is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. It can be used as follows:

Indications for Use	Putty	Paste
Ridge augmentation	√	√
Filling of extraction sites	√	√
Craniofacial augmentation	√	√
Mandibular reconstruction	√	√
Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture	√	√
Filling resection defects in benign tumors, benign cysts, or other osseous defects in the alveolar ridge wall	√	√
Filling of cystic defect	√	√
Filling of lesions of periodontal origin	√	√
Filling of defects of endodontic origin	√	√

DBX[®] Inject is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. DBX[®] Inject can be used with bone marrow. DBX[®] Inject is for single patient use only.

Substantial Equivalence

This submission supports the position that DBX[®] Inject is substantially equivalent to a number of previously cleared devices, including:

DBX[®] Demineralized Bone Matrix - Musculoskeletal Transplant Foundation [K040262]
Signal[™] DBM-Musculoskeletal Transplant Foundation [K080405]

When comparing DBX[®] Inject to its predicate devices, there are no new types of safety and effectiveness questions. DBX[®] Inject has been demonstrated to be substantially equivalent to its predicate devices.