K091955

510(k) Summary of Safety and Effectiveness
Stryker SonicPin™ System

APR - 2 2010

Proprietary Name:	Stryker SonicPin™ System
Common Name:	Smooth Fixation Pin
Classification Name/Reference:	Smooth or threaded metallic bone fixation fastener, 21 CFR §888.3040
Device Product Code:	87 HTY
Proposed Regulatory Class:	Class II
For Information contact:	Avital Merl-Margulies Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-3365
Date Summary Prepared:	February 1, 2010

Description:

The Stryker SonicPin™ System consists of a bioresorbable implant pin made of a PLDLA copolymer and an ultrasonic unit (generator and sonotrode). Pins are implanted using ultrasonic energy generated by an ultrasonic unit, allowing the pin to adapt to the previously drilled hole. Its intended use is the correction of the Hallux Valgus deformation.

Indications:

The Stryker SonicPin™ System is intended to maintain alignment and fixation of bone fractures, osteotomies, or bone grafts in hallux valgus applications in the presence of appropriate immobilization (e.g. rigid fixation implants, cast, brace). The Stryker SonicPin™ is designed only to be inserted with the ultrasonic driver of the Stryker SonicPin™ System.

Substantial Equivalence:

The Stryker SonicPin™ System is substantially equivalent to the INION OTPS™ Pin, Synthes® POLYPIN™ 2.0, Howmedica Bioabsorbable Pin, as well as the KLS-Martin, L.P. RESORB-X SF® in regards to intended use, indications for use, technological characteristics, design, materials, and operational principles as a fracture fixation system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
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325 Corporate Drive
Mahwah, NJ 07430

APR - 2 2010

Re: K091955
Trade/Device Name: Stryker SonicPin System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fastener
Regulatory Class: Class II
Product Code: HTY
Dated: February 1, 2010
Received: February 2, 2010

Dear Ms. Merl-Margulies:

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.

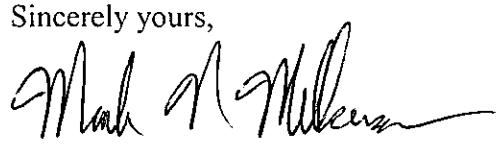
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Indications for Use

510(k) Number (if known): K091955

Device Name: Stryker SonicPin™ Pin System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091955