K061493

JUL - 7 2006

510(k) Summary of Safety and Effectiveness
Apex® Pins with HA Coating

Proprietary Name:	Apex® Pins
Common Name:	External Fixation Pins
Classification Name/Reference:	Smooth or threaded metallic bone fixation fastener - 21 CFR §888.3040
Device Product Code:	87 JDW
Proposed Regulatory Class:	Class II
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	May 30, 2006

Description
This submission is a line extension to the Apex® Pin product line to include fixation pins coated with hydroxylapatite (HA) to improve purchase in osteoporotic bone and for use in long-term fixation to reduce the incidence of pin loosening by enhancing the fixation at the pin-bone interface. The Apex® Pins are external fixation pins used with external fixators for fracture fixation. They are intended to be used with the other components in Howmedica Osteonics' external fixation systems.

Indications:

Apex® Pins are intended for use in conjunction with external fixators in children and adults. Specific indications include, but not limited to the following conditions: bone fracture fixation for open, closed and/or unstable fractures, osteotomies, arthrodeses, deformity correction including bone transport, revision procedures where other treatments or devices have been unsuccessful or bone reconstruction procedures. The pins will be available with and without hydroxylapatite (HA) coating.

Substantial Equivalence:

Apex® Pins with hydroxylapatite (HA) coating are substantially equivalent to other commercially available uncoated and HA coated pins in regards to intended use, design, materials, and operational principles as external fixation pins. Testing was conducted to compare the subject HA coated pins to its uncoated predicate for mechanical strength and to characterize the HA coating. The results demonstrate that the subject pins are substantially equivalent in strength to the predicate pins with and without HA coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2006

Stryker Howmedica Osteonics Corp.
% Ms. Vivian Kelly
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K061493
Trade/Device Name: Apex® Pins
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: May 30, 2006
Received: May 31, 2006

Dear Ms. Vivian Kelly:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K061493

Device Name: Apex® Pins

Indications for Use:

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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 General, Restorative, and Neurological Devices

510(k) Number K061493