AUG - 4 2006

K053348

510(k) Summary of Safety and Effectiveness
Stryker® Orthopaedics RFID Instrumentation

Proprietary Name:	Stryker® Orthopaedics RFID Instrumentation
Common Name:	Orthopedic Manual Surgical Instruments with RFID capability
Classification Name and Reference:	Stereotaxic instrument (Title 21 CFR §882.4560)
Device Panel/Product Code:	84 HAW
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:	November 30, 2005

Description
Stryker® Orthopaedics RFID Instrumentation are navigational compatible manual surgical instruments which contain radio-frequency identification (RFID) technology. The RFID tags on the instruments are passive and will not operate without the navigation system. These instruments will be used during orthopedic surgery in conjunction with the Stryker® Navigation System. The instrumentation will be maintained and distributed by Stryker® Orthopaedics, while the navigation system will be maintained and distributed by Stryker® Instruments.

Indications:
Stryker® Orthopaedics RFID Instrumentation is intended for use as accessories to the Stryker® Navigation System's Hip and Knee Modules during orthopedic surgery.

Substantial Equivalence:
The Stryker® Orthopaedics RFID Instrumentation is substantially equivalent to other navigational compatible instruments in regards to intended use, design, materials, and operational principles. The following devices are examples of predicate devices: 1) Hip and Knee Modules of the Stryker® Navigation System (K022365 and K010204), 2) Smith and Nephew Image Guided Surgical Instruments (K033341) and 3) DePuy CAS Knee Instrumentation (K043223).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

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

Re: K053348
Trade/Device Name: Stryker® Orthopaedics RFID Instrumentation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 27, 2006
Received: July 28, 2006

Dear Ms. 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) 276-0115. 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,

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

Enclosure

K053348

Indications for Use

510(k) Number (if known): _____

Device Name: Stryker® Orthopaedics RFID Instrumentation

Indications

Stryker® Orthopaedics RFID Instrumentation is intended for use as accessories to the Stryker® Navigation System's Hip and Knee Modules during orthopedic surgery.

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 K053348