K071092 1/1

Summary of Safety and Effectiveness

Asnis™ III Cannulated Screw System Line Extension

MAY 11 2007

Proprietary Name:	Asnis™ Micro Cannulated Screw
Common Name:	Bone Screw
Classification Name and Reference:	Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040
Proposed Regulatory Class:	Class II
Device Product Code:	87 HWC: Screw, Fixation, Bone
For Information contact:	Vivian Kelly, Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	April 17, 2007

Description:
This Special 510(k) submission is a line extension to address modifications to the Asnis™ III Cannulated Screw System. This line extension is to add additional sizes of screws to the system.

Intended Use
The modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject device are provided below.

Indications
The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Substantial Equivalence:
These additional components are substantially equivalent to their predicate systems in respect to design, intended use, performance and operational principle as internal fixation components. Predicate systems include the Asnis™ III Cannulated Screw System (K000080 and K024060) and other commercially available cannulated screws on the market such Vilex 2mm Screws (K973309, K991151 & K991197) and Synthes Cannulated Screws (K962823.) Mechanical testing was conducted to compare the strength of the subject device to predicate screws. The results demonstrate that the subject components are substantially equivalent in strength to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 2007

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

Re: K071092
Trade/Device Name: Asnis™ III Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth of threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 17, 2007
Received: April 18, 2007

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) 276-0120. 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 K071092

510(k) Number (if known):

Device Name: Asnis™ III Cannulated Screw System

Indications for Use:

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K071092