

NOV 23 1998

**510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Osteo 5.0mm Cannulated Screw System**

K983006

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Kate Sutton
Regulatory Affairs Specialist

Date Summary Prepared:

August 26, 1998

Device Identification

Proprietary Name:

Osteo 5.0mm Cannulated
Screw System

Common Name:

Cannulated Screw

Classification Name and Reference:

Smooth or Threaded Metallic Bone Fixation
Fastener
21 CFR §888.3040

Predicate Device Identification

The subject components of the Osteo 5.0mm Cannulated Screw System are substantially equivalent to the components of the Synthes Titanium 4.5mm Cannulated Screw and the 4.5mm & 5.0mm cannulated screws in the ACE Medical Titanium Cannulated Screw and Reconstruction Plate System.

Device Description

The Osteo 5.0mm Cannulated Screw System consists of 5.0mm thread diameter self-tapping cannulated screws of varying lengths and one washer, the use of which is optional. The 5.0mm screw has a thread diameter of 5.0mm, a shaft diameter of 3.2mm, a head diameter of 6.0mm, and a cannulation diameter of 2.0mm. The washer for the 5.0 screws has an outer diameter of 8.0mm, an inner diameter of 4.5mm, and a thickness of 1.0mm. The surfaces of the screws and washers are anodized with a Type II coating. The screws and washers are provided both sterile and non-sterile.

Intended Use

The Osteo 5.0mm Cannulated Screw System is indicated for ligament fixation and long and small bone fracture fixation, which may include the following:

- Fixation of intermediate-sized fragments in fractures such as:
 - proximal and distal humerus fractures
 - fractures of the olecranon process
 - femoral fractures
 - tibial plateau and metaphyseal fractures of the proximal and distal tibia
 - medial and lateral malleolar and pilon fractures
 - os calcis, talar, and patellar fractures
- Ligament fixation of the proximal humerus
- Fractures of the pelvis and acetabulum
- Arthrodesis of the tarsals

Statement of Technological Comparison

The subject components of the Osteo 5.0mm Cannulated Screw Systems are substantially equivalent in design and intended use to the predicate devices offered by Synthes and ACE Medical.



NOV 23 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Elizabeth A. Staub
Director, Quality Assurance and Regulatory Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K983006
Trade Name: Osteonics 5.0mm Cannulated Screw System
Regulatory Class: II
Product Code: HWC
Dated: August 26, 1998
Received: August 28, 1998

Dear Ms. Staub:

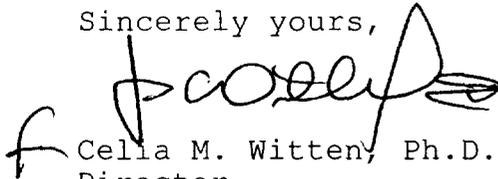
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983006

Device Name: Osteo 5.0mm Cannulated Screw Systems

Indications For Use:

The Osteo 5.0mm Cannulated Screw Systems are indicated for ligament fixation and long and small bone fracture fixation, which may include the following:

For ø5.0mm Cannulated Screws:

- Fixation of intermediate-sized fragments in fractures such as:
 - proximal and distal humerus fractures
 - fractures of the olecranon process
 - femoral fractures
 - tibial plateau and metaphyseal fractures of the proximal and distal tibia
 - medial and lateral malleolar and pilon fractures
 - os calcis, talar, and patellar fractures
- Ligament fixation of the proximal humerus
- Fractures of the pelvis and acetabulum
- Arthrodesis of the tarsals

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

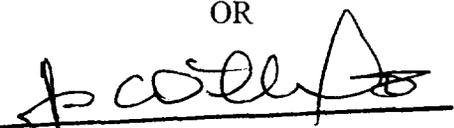
Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K983006