

DEC - 3 1998

K983165

**510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Osteo 4.0mm Cannulated Screw System - Expanded Indications**

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:

September 2, 1998

Device Identification

Proprietary Name:

Osteo 4.0mm 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 4.0mm Cannulated Screw System are substantially equivalent to the components of the Richards 4.0mm Cannulated Screw and the 4.0mm cannulated screws in the ACE Medical Titanium 3.5/4.0mm Small Fragment System. The ACE Medical 4.0mm Cannulated Screws are indicated for fractures of the fibula and os calcis, and the Richards 4.0mm Cannulated Screws are indicated for fractures of the medial malleolus.

Device Description

The Osteo 4.0mm Cannulated Screw System consists of 4.0mm thread diameter self-tapping cannulated screws of varying lengths and one washer, the use of which is optional. All components of the system are provided sterile and non-sterile. The screw and washer are manufactured from Titanium 6Al-4V ELI alloy. The screw has a thread diameter of 4.0mm. The washer has an outer diameter of 7.0mm and an inner diameter of 4.0mm. The surfaces of the screws and washers are anodized with a Type II coating.

Intended Use

The Osteo 4.0mm Cannulated Screw System is indicated for osteochondritis dissecans, ligament fixation, and long and small bone fracture fixation, which may include the following:

- Fractures of the olecranon, distal humerus
- Fractures of the ulna and radius
- Patellar fractures
- Distal tibia and pilon fractures
- Fractures of the tarsals and metatarsals
- Tarso-metatarsal and metatarso-phalangeal arthrodeses
- Metatarsal and phalangeal osteotomies
- Fractures of the posterior wall of the acetabulum and other fractures of the pelvic ring
- Fractures of the fibula, medial malleolus, and os calcis
- Other small fragment, cancellous bone fractures

Statement of Technological Comparison

The subject components of the Osteo 4.0mm Cannulated Screw Systems are substantially equivalent in design and intended use to the predicate devices offered by Richards and ACE Medical.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kate Sutton
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K983165
Osteo 4.0mm Cannulated Screw System
Regulatory Class: II
Product Code: HWC
Dated: September 4, 1998
Received: September 10, 1998

Dear Ms. Sutton:

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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and
2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this

device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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.

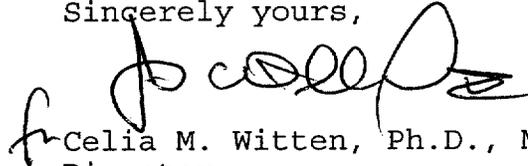
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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,



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): K 983165

Device Name: Osteo 4.0mm Cannulated Screw Systems - Expanded Indications

Indications For Use:

The indications for the use of these cannulated screws, in keeping with those of other legally marketed cannulated screws, are as follows.

The Osteo 4.0mm Cannulated Screw System is indicated for osteochondritis dissecans, ligament fixation, and long and small bone fracture fixation, which may include the following:

- Fractures of the olecranon, distal humerus
- Fractures of the ulna and radius
- Patellar fractures
- Distal tibia and pilon fractures
- Fractures of the tarsals and metatarsals
- Tarso-metatarsal and metatarso-phalangeal arthrodeses
- Metatarsal and phalangeal osteotomies
- Fractures of the posterior wall of the acetabulum and other fractures of the pelvic ring
- Fractures of the fibula, medial malleolus, and os calcis
- Other small fragment, cancellous bone fractures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983165

Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)