

**510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEO CANNULATED SCREW SYSTEM**

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:

May 14, 1997

Device Identification**Proprietary Name:**

Osteo Cannulated Screw System

Common Name:

Cannulated Screws

Classification Name and Reference:

Smooth or Threaded Metallic Bone Fixation Fastener
21 CFR §888.3040

Predicate Device Identification

The subject components of the Osteo Cannulated Screw System are substantially equivalent to the components of the Smith & Nephew 6.5mm Universal Cannulated Screw System, the Smith & Nephew 8.0mm Cannulated Screw System, and the Synthes 7.3mm Cannulated Screw System.

Device Description

The Osteo Cannulated Screw System consists of three self-tapping cannulated screws of various lengths, and one washer, which can accommodate any one of the three screws. All devices in the system are provided both sterile and non-sterile. The three screws and washer are manufactured from Titanium 6Al-4V alloy. Two of the three screws have a thread diameter of 6.5mm. One of the two 6.5mm screws has a thread length of 20mm, while the other has a thread length of 40mm. The third screw has an 8.0mm thread diameter and a 25mm thread length. The washer has an outer diameter of 14mm and an inner diameter of 7.5mm.

Intended Use

The Osteo Cannulated Screw System is indicated for the following:

- Intracapsular fractures of the femoral neck
- Intertrochanteric fractures of the femur
- Tibial plateau fractures
- Fractures of the dorsal pelvic ring
- Pelvic sacroiliac joint disruptions
- Ankle arthrodesis

Statement of Technological Comparison

The subject Osteo Cannulated Screw System components are substantially equivalent in design and intended use to the predicate devices offered by Smith & Nephew Richards and Synthes. Both the subject screws and some predicate Synthes screws are manufactured from Titanium alloys.



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: K971800
Osteo Cannulated Screw System
Regulatory Class: II
Product Code: HWC
Dated: May 14, 1997
Received: May 15, 1997

JUL 30 1997

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:

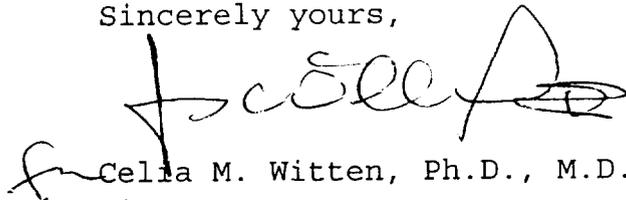
1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and
2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device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

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): K971800

Device Name: Osteo Cannulated Screw System

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 Cannulated Screw System is indicated for the following:

- Intracapsular fractures of the femoral neck
- Intertrochanteric fractures of the femur
- Tibial plateau fractures
- Fractures of the dorsal pelvic ring
- Pelvic sacroiliac joint disruptions
- Ankle arthrodesis

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Concurrence of CDRH, Office of Device Evaluation (ODE)

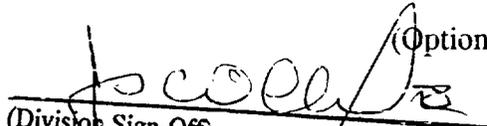
Prescription Use X

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 K971800