JUN 27 1997

K971778
1 of 2

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEO SMALL AND MINI BONE SCREWS

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:

Donna S. Wilson
Regulatory Affairs Specialist

Date Summary Prepared:

May 13, 1997

Device Identification

Proprietary Name:

Osteo Small and Mini Bone Screws

Common Name:

Bone Screws

Classification Name and Reference:

Smooth Or Threaded Metallic Bone Fixation Fastener - 21 CFR §888.3040

Predicate Device Identification

The Osteo Small and Mini Cortex Screws are substantially equivalent to the Synthes Small and Mini Cortex Screws. The Osteo Small and Mini Cancellous Screws are substantially equivalent to the Howmedica Small and Mini Bone Screws.

Device Description

Small Cortex Screws:

The Osteo Small Cortex Screws are fabricated from ASTM F-138-92 stainless steel, and feature a self tapping thread with three cutting grooves. The thread diameter measures 2.5mm, and the root diameter measures 1.9mm. These bone screws have a hexagonal head with a spherical underside. The hexagonal head measures 5mm in diameter. The Osteo Small Cortex Screws are available in lengths from 6mm to 40mm.

Mini Cortex Screws:

The Osteo Mini Cortex Screws are fabricated from ASTM F-138-92 stainless steel, and are available either with or without a self tapping thread. The thread on the self tapping screws features one cutting groove. The thread diameter measures 1.5mm, and the root diameter measures 1.0mm. These bone screws have a conical head underside with a cross slot. The head measures 2.5mm in diameter. The Osteo Mini Cortex Screws with a self tapping thread are available in

lengths from 8mm to 22mm. The Osteo Mini Cortex Screws without a self tapping thread are available in lengths from 6mm to 20mm.

Small Cancellous Screws:
The Osteo Small Cancellous Screws are fabricated from ASTM F-138-92 stainless steel. The thread diameter measures 4.0mm, and the root diameter measures 1.9mm. These bone screws have a hexagonal head with a spherical underside. The hexagonal head measures 6mm in diameter. The Osteo Small Cancellous Screws are available in lengths from 10mm to 60mm.

Mini Cancellous Screws:
The Osteo Mini Cancellous Screws are fabricated from ASTM F-138-92 stainless steel, and feature a self tapping thread. The self tapping thread features one cutting groove. The thread diameter measures 2.2mm, and the root diameter measures 1.1mm. These bone screws have a flat head with a cross slot. The head measures 3.0mm in diameter. The Osteo Mini Cancellous Screws are available in lengths from 8mm to 22mm.

Intended Use
The subject Osteo Small and Mini Bone Screws are intended for internal fracture fixation of small bones. Osteo Bone Screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Osteo Small and Mini Bone Screws are available in non-sterile and sterile offerings.

Statement of Technological Comparison
The subject Osteo Small and Mini Bone Screws are substantially equivalent in materials (stainless steel), design (small and mini cortex and cancellous bone screws), and intended use (internal fracture fixation of small bones) to the predicate devices offered by Synthes and Howmedica.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Donna S. Wilson
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

JUN 27 1997

Re: K971778
Osteo Small and Mini Bone Screws
Regulatory Class: II
Product Code: HWC
Dated: May 13, 1997
Received: May 14, 1997

Dear Ms. Wilson:

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,

Marie A. Schroeder, MS, PT

for 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): K971778

Device Name: Osteo Small and Mini Bone Screws

Indications For Use:

The subject Osteo Small and Mini Bone Screws are intended for internal fracture fixation of small bones. Osteo Bone Screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

(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 K971778