SEP 2 2 1998

K982553



# 510(k) PREMARKET NOTIFICATION
# SUMMARY OF SAFETY AND EFFECTIVENESS
# OSTEO COMPRESSION HIP SCREW SYSTEM - EXPANDED INDICATION

## 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:**

Marybeth Naughton
Regulatory Affairs Team Member

**Date Summary Prepared:**

July 17, 1998

## Device Identification

**Proprietary Name:**

Osteo Compression Hip Screw System

**Common Name:**

Compression Hip Screw Plate and Screw

**Classification Name and Reference:**

Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
21 CFR §888.3030

## Predicate Device Identification

The expanded indication of the subject components of the Osteo Compression Hip Screw System, which is the subject of this premarket notification, are substantially equivalent to the indications of the components of the Synthes DHS® Dynamic Hip Screw System.

## Device Description

The Osteo Compression Hip Screw System is a proximal femoral fracture fixation system, comprised of compression hip screw plates, lag screws, and a compression screw, which is intended to provide strong and stable internal fixation with minimal soft tissue irritation. Osteo Cortical Bone Screws may be utilized with this system for additional compression and fixation. This system is utilized as an aid to healing, not as a substitute for normal intact tissues. The design and materials for the Osteo Compression Hip Screw System are determined to be substantially equivalent via 510(k)s #K971654, #K971321 and #K920037, and remain unchanged from these previous submissions.

## Intended Use

The Osteo Compression Hip Screw System is cleared for use via 510(k)s #K971654, #K971321 and #K920037 for the following indications: Intertrochanteric femoral fractures and intracapsular femoral neck fractures. The expanded indications for the Osteo Compression Hip Screw System include: extracapsular fractures of the proximal femur (basal neck fractures, trochanteric fractures, and subtrochanteric fractures).

## Statement of Technological Comparison

The subject Osteo Compression Hip Screw System components are substantially equivalent in intended use to the predicate devices offered by Synthes in their DHS® Dynamic Hip Screw System.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Ms. Marybeth Naughton
Regulatory Affairs Team Member
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K982553
Trade Name: Osteo Compression Hip Screw System
Regulatory Class: II
Product Code: HRS, HWC
Dated: July 21, 1998
Received: July 22, 1998

Dear Ms. Naughton:

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 (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. 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 at (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): K971654, K971321, K920037

Device Name: Osteo Compression Hip Screw System - Expanded Indication

Indications For Use:

The Osteo Compression Hip Screw System is a proximal femoral fracture fixation system, comprised of compression hip screw plates, lag screws, and a compression screw, which is intended to provide strong and stable internal fixation with minimal soft tissue irritation. It is a system which optimally engages the femoral head and permits impaction of bone fracture fragments. The Osteo I-C Humeral Nail System is intended for single use only.

**Indications:**

Cleared via 510(k)s #K971654, #K971321, #K920037

- Intracapsular fractures of the femoral neck
- Intertrochanteric fractures

Expanded Indication (the subject of this premarket notification)

- Extracapsular fractures of the proximal femur:
  - basal neck fractures
  - trochanteric fractures
  - subtrochanteric fractures

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

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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 K982553