DEC 7 1998

K980508

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEO COMPRESSION CONDYLE 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:

Marybeth Naughton
Regulatory Affairs Team Member

Date Summary Prepared:

October 6, 1998

Device Identification

Proprietary Name:

Osteo Compression Condyle Screw System

Common Name:

Compression Condyle Plate and Screw

Classification Name and Reference:

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

Predicate Device Identification

The Osteo Compression Condyle Screw System has previously been determined substantially equivalent via 510(k0s #K971321 and #K920037. The expanded indications are substantially equivalent to those of the Synthes® Dynamic Condylar Screw System.

Device Description

The Osteo Compression Condyle Screw System is a distal and proximal femoral fracture fixation system, comprised of compression condyle plates, lag screws, and a compression screw, which is intended to provide strong and stable internal fixation with minimal soft tissue irritation. Osteo cancellous and 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 #K920037 and #K971321, and remain unchanged from these previous submissions.

Intended Use

The Osteo Compression Condyle Screw System is indicated for the following fractures of the distal femur: Intercondylar fractures, Supracondylar fractures, and Unicondylar fractures and for the following fractures of the proximal femur: Transverse subtrochanteric fractures, and long and short subtrochanteric fractures.

Statement of Technological Comparison

The subject Osteo Compression Condyle Screw System components (compression condyle plates and lag screws) have been previously determined substantially equivalent in design and materials, and are substantially equivalent with regard to intended use to the predicate devices offered by Synthes in their Dynamic Condylar Screw System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 1998

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

Re: K983508
Osteo Compression Condyle Screw
System - Expanded Indications
Regulatory Class: II
Product Code: HWC
Dated: November 11, 1998
Received: November 12, 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

K983508

510(k) Number (if known): ~~K#K920037, #K971321~~

Device Name: Osteo Compression Condyle Screw System - Expanded Indications

Indications for Use:

The Osteo Compression Condyle Screw System is a femoral fracture fixation system, comprised of compression condyle plates, lag screws, and a compression screw, which is intended to provide strong and stable internal fixation with minimal soft tissue irritation. Osteo cancellous and cortical bone screws (#K913269) 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.

Indications

Cleared via 510(k) #K971321 and 510(k) #K920037

- Intercondylar fractures
- Supracondylar fractures
- Unicondylar fractures

Expanded Indications (the subject of this premarket notification)

Fractures of the proximal femur:

- Transverse subtrochanteric fractures
- Short oblique subtrochanteric fractures
- Long oblique subtrochanteric fractures

The Osteo Compression Condyle Screw System is used in the proximal femur in situations which require a more proximal placement of the lag screw in the femoral head, which the 95 degree plate angle accommodates. This allows for the placement of one or more bone screws in the proximal fragment which is intended to result in greater stability in the proximal femur, transmission of load across the fracture site and control of the rotation and translation of the fracture fragment

(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 K983508