

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

JUL - 9 1997

**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:**

April 9, 1997

**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 is substantially equivalent to the Synthes® Dynamic Condylar Screw System.

**Device Description**

The Osteo Compression Condyle Screw System is a distal 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.

*Osteo Compression Condyle Plates:*

The Osteo Compression Condyle Plates are part of the Osteo Compression Condyle Screw System. These plates are fabricated from ASTM F-138 Stainless Steel (Grade 2, 316LVM), and are offered both non-sterile and sterile. The Osteo Compression Condyle Plates are available in four (4) sizes with varying lengths and number of screw holes (6, 8, 10, and 12) for varied clinical situations. All plates have a 25mm barrel length and autocompression holes for cortical

screws with a 4.5mm diameter. The two screw holes closest to the barrel also accommodate cancellous screws with a 6.5mm diameter. The plates feature a 95° barrel angle. The barrel slides over the inserted lag screw; a compression screw may be used for additional compression of the fracture area.

*Osteo Lag Screws:*

The Osteo Lag Screws which are included as part of this premarket notification are available in three lengths (50mm, 55mm, and 60mm). Osteo Lag Screws of longer lengths, up to 145mm, have been cleared under a previous premarket notification. The subject Osteo Lag Screws are fabricated from ASTM F-138 Stainless Steel (Grade 2, 316LVM), and are offered both non-sterile and sterile. All lag screws have a 22mm thread length for maximum purchase, a thread diameter of 12.5mm, and a cannulated end for ease of use with guide instrumentation.

**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.

**Statement of Technological Comparison**

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



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

JUL - 9 1997

Re: K971321  
Osteo Compression Condyle Screw System  
Regulatory Class: II  
Product Codes: HRS and HWC  
Dated: April 9, 1997  
Received: April 10, 1997

Dear Ms. Wilson:

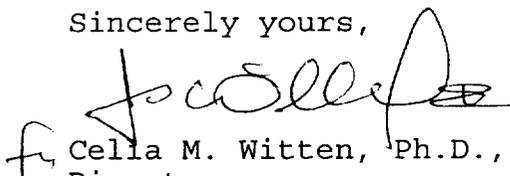
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,

  
f Cella 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): K971321

Device Name: Osteo Compression Condyle Screw System

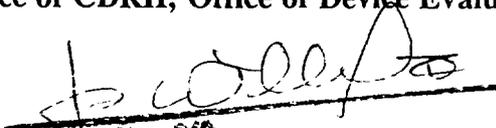
**Indications For Use:**

The Osteo Compression Condyle Screw System is a distal 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 Osteo Compression Condyle Screw System is indicated for the following fractures of the distal femur:

- Intercondylar fractures
- Supracondylar fractures
- Unicondylar fractures

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division of ~~Regulatory~~ ~~Medical~~ ~~Devices~~)  
Division of ~~Regulatory~~ ~~Medical~~ ~~Devices~~  
510(k) Number K971321

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)