

MAY 5 1998

Osteonics® FX-Cablelok™ Grip Components

510(k) Premarket Notification

K980594

**510(K) SUMMARY**

**OSTEONICS® FX-CABLELOK™ GRIP COMPONENTS**

**Submission Information**

**Name and Address of the Sponsor:**

Osteonics Corporation  
59 Route 17  
Allendale, NJ 07401-1677

**Contact Person:**

Donna S. Wilson  
Regulatory Affairs Specialist

**Date of Summary Preparation:**

February 16, 1998

**Device Identification**

**Proprietary Name:**

Osteonics® FX-Cablelok™ Grip  
Components

**Common Name:**

Bone Fixation Accessory

**Classification Name and Reference:**

CFR §888.3030

**Predicate Device Identification**

The subject devices are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Howmedica Dall Miles Cable Grip System and Mini Cleat
- FX-Cablelok™ System

**Device Description**

The subject devices are characterized by the following design features: Staple like grip design with proximal and distal hooks used in conjunction with trochanteric cable and crimp sleeves.

**Intended Use**

The Osteonics® FX-Cablelok™ Grip Components are intended for use with the Osteonics® FX-Cablelok™ System cable and sleeve components to provide fixation of the greater trochanter secondary to osteotomy in total hip replacement arthroplasty, surface replacement arthroplasty or any hip procedure requiring a trochanteric osteotomy.

**Indications**

- Trochanteric reattachment

**Statement of Technological Comparison:**

The substantial equivalence of the subject device is supported by a comparison of the subject device to the above-cited predicate devices. A comparison of the subject and predicate devices in terms of intended use, materials, and design follows:

*Intended Use* - Trochanteric reattachment

*Materials* - Cobalt chromium alloy

*Design* - Staple like grip design used with cable and crimp sleeves.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 5 1998

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

Re: K980594  
Trade Name: Osteonics® FX-Cablelok™ Grip Components  
Regulatory Class: II  
Product Codes: LYT and JDQ  
Dated: February 16, 1998  
Received: February 17, 1998

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.

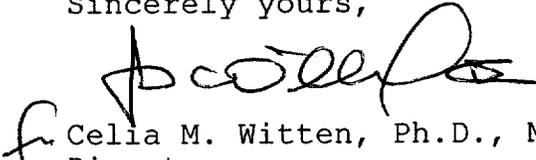
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Donna S. Wilson

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,



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

