2/24/99

K984432

510(k) Summary

Proprietary Name: Dall-Miles Cable Grip

Common Name: Bone Fixation Cerclage

Classification Name and Reference: Bone Fixation Cerclage
21 CFR 888.3010

Proposed Regulatory Class: Class II

Device Product Code: OR(87) JDQ

For information contact: Frank Maas
Manager, Regulatory Affairs
Howmedica Osteonics
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Date Summary Prepared: 12-11-98

The Dall-Miles Cable Grip (A-Grip) described in this submission is a modification of the previously cleared Osteonics FX-Cablelok™ grip components. The intended use of the modified device is the same as the current device; for the fixation of the greater trochanter secondary to osteotomy in total hip replacement, surface replacement arthroplasty, or any hip procedure requiring a trochanteric osteotomy. The vertical fixation feature of the device aids in the fixation of the trochanter in those instances where additional stabilization may be required, for example revision cases. These grips are intended to be used in conjunction with the Dall-Miles cables and sleeves and the FX-Cablelok System.

The design modifications are outlined below:

The two proximal hooks in the current grip have been reduced to one centrally positioned hook in the new grip. This central hook is available with and without a cannulated groove for the passage of cable. A hole in the central hook allows for the passage of cable that provides the vertical fixation feature of the device.

The flares on the anterior and posterior limbs (used for the passage of cable during vertical fixation) have been removed. Two new designs have been developed to provide for vertical fixation. The first design incorporates a crimping mechanism in each of the distal hooks of the grip. The cable is passed through the grip and a "tension band" device (that is placed below the trochanter, similar to the existing FX-Cablelok sleeve design) and secured by crimping the hooks on the grip. The second design incorporates a crimping mechanism directly in the tension band component. With this design, the cable is passed through the grip and the tension band device and secured by crimping the tension band component.

The standard method for horizontal fixation on the current design is still provided in both of the new designs.

The substantial equivalence of the modified Dall-Miles Grip is based on the equivalence in intended use, materials, design, operational principles, and indications and contraindications to Osteonics' FX-Cablelok Grip Components (K980594) and Howmedica's Dall-Miles Trochanter Cable Grip System (K844068, K900926, and K971741).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Mr. John Dichiara
Director of Regulatory Affairs
and Public Policy
Howmedica Inc.
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K984432
Trade Name: Dall-Miles Cable Grip Modification
Regulatory Class: II
Product Code: JDQ and LYT
Dated: December 11, 1998
Received: December 14, 1998

Dear Mr. Dichiara:

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,

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

Indications for Use

510(k) Number (if known): K984432

Device Name: Dall-Miles Cable Grip (A-Grip)

Indications for Use:

The Dall-Miles Cable Grip is intended to be used for the fixation of the greater trochanter secondary to osteotomy in total hip replacement, surface replacement arthroplasty, or any hip procedure requiring a trochanteric osteotomy.

(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 Restorative Devices
510(k) Number K984432