

K97174)  
510(k) Summary

JUL 16 1997

Proprietary Name: Dall-Miles Homogeneous Stainless Steel Cable and Beaded Cable

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 Inc.  
359 Veterans Boulevard  
Rutherford, NJ 07070  
Telephone: (201) 507-7875  
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Date Summary Prepared: 5-9-97

The Dall-Miles Homogeneous Stainless Steel Cable and Beaded Cable described in this submission are modifications of the existing cable and beaded cable. The difference between the new stainless steel devices and the existing cables cleared in submissions K844068 and K961569 is the material (22-13-5 ESR vs. 316L) and the manner in which the cable is manufactured (Homogeneous strands vs. Non-Homogeneous). There are no other differences in the design, manufacturing method, or principles of operation between the two types of cables.

The Dall-Miles Homogeneous Stainless Steel Cable and Beaded Cable are intended to be used for spinal wiring, sternotomy applications, cerclage procedures, and trauma surgery of the shoulder, elbow, knee, hip, or ankle. In addition, these cables may be used for supplementary fracture fixation when used with bone plates and screws and for the stabilization of bone graft material.

The substantial equivalence of the Dall-Miles Cable and Beaded Cable is based on the equivalence in intended use, materials, design, operational principles, and indications and contraindications to Howmedica's Dall-Miles Trochanter Cable Grip System (K844068 & K900926); Dall-Miles Homogeneous Cable, Vitallium® (K945294); Dall-Miles Suture/Beaded Cable (K953818); and Dall-Miles Stainless Steel Beaded Cable, 316L (K961569).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Frank Maas  
Manager, Regulatory Affairs  
Howmedica Inc.  
Pfizer Hospital Products Group  
359 Veterans Boulevard  
Rutherford, New Jersey 07070-2584

JUL 16 1997

Re: K971741  
Dall Mile Homogeneous Stainless  
Steel Cable and Beaded Cable  
Regulatory Class: II  
Product Code: JDQ  
Dated: May 9, 1997  
Received: May 12, 1997

Dear Mr. Maas:

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.

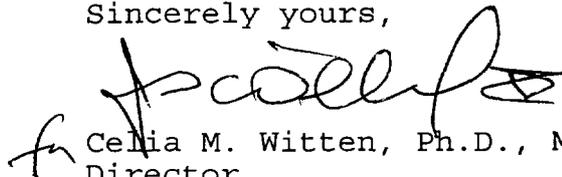
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

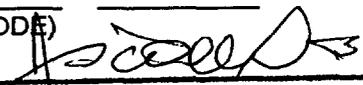
Device Name: Dall-Miles Homogeneous Stainless Steel Cable and Beaded Cable  
Modification

Indications for Use:

The Dall-Miles Homogeneous Stainless Steel Cable and Beaded Cable are intended to be used for spinal wiring, sternotomy applications, cerclage procedures, and trauma surgery of the shoulder, elbow, knee, hip, or ankle. In addition, these cables may be used for supplementary fracture fixation when used with bone plates and screws and for the stabilization of bone graft material.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number 1697174

Prescription Use X OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)