

OCT 27 1999

K992616

V. 510(K) SUMMARY

***Pioneer Surgical Technologies
510(K) Notification Summary
For
SDB Cerclage System***

Administrative Information

Manufacturer Identification and Sponsor: Pioneer Surgical Technologies
375 River Park Circle
Marquette, MI 49855-1781
Telephone: 906-226-9909
FAX: 906-226-9932

Official Contact: Burns Severson
Senior Vice President,
Regulatory Affairs/Quality Assurance

Date Prepared: 7/23/99

Device Identification

Proprietary Name: SDB Cerclage System
Common Name: Cerclage, Bone Fixation
Classification Name and Reference: Cerclage, Bone Fixation
Regulation Number: CFR 888.3010
Classification Number: 87JDQ
Device Class: II

Devices on Which Substantial Equivalence is Claimed:

1. Dall Miles "Trochanter Cable Grip System" - K844068;
2. Dall Miles "Modified Trochanter Cable Grip System" - K872224;
3. Dall Miles "Trochanter Cable Grip System (Additional Indications)" - K900926; and
4. Stainless Steel cerclage wire, manufactured prior to 1976

V. **510(K) SUMMARY (Continued)**

Device Description

The SDB Cerclage System consists of two diameter cable sizes each in association with a double holed crimp. The cable is routed around the bone through a Cable Passer and back through the adjacent hole in the crimp. The free end of the cable is passed through the Tensioner instrument and tensioned to the desired level of construct compression with guidance provided by the tensioner scale. A Crimper instrument is introduced and interfaced with the crimp followed by the squeezing of the instruments handles and the release of the pawl indicating a full crimping cycle has been obtained. The excess cable is then trimmed with a cutter.

The SDB Cerclage System shall be supplied with the cable and crimp assembled and packaged sterile as a single-use item.

Intended Use

The SDB Cerclage System devices will be offered in two sizes of cable constructs. The large cable construct shall be indicated for the following: general orthopedic trauma surgery involving olecranon, patella, femur, pelvic, acetabular, humeral and ankle fractures, acromioclavicular dislocations, prophylactic banding during total joint procedures, and temporary reduction techniques for ORIF (Open Reduction Internal Fixation) procedures. The small cable size shall be contraindicated for use in the femur ORIF and prophylactic banding during total joint procedures.

Technological Characteristic Compared to Predicate Device

The Large SDB Cerclage System devices have the same double holed crimp and squeezing technique as the predicate Howmedica Dall-Miles Cable Grip System (K844068, K872224, & K900926). The Small SDB Cerclage System devices have similar cable diameters as the 18g stainless steel monofilament wire.

Performance Data

The Large SDB Cerclage System cable constructs and its predicate device Howmedicas Dall-Miles 1.6mm cable constructs were tested in static yield and fatigue. In both tests and for each type of construct, the cerclage cable was the failure mode with the SDB Cerclage System displaying equivalence to the Dall-Miles 1.6mm System under each of the testing conditions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1999

Mr. Burns O. Severson
Senior Vice President, Regulatory Affairs/Quality Assurance
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855

Re: K992616
Trade Name: SDB Cerclage System
Regulatory Class: II
Product Code: JDQ
Dated: August 2, 1999
Received: August 4, 1999

Dear Mr. Severson:

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.

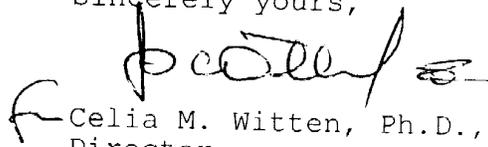
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

K992616

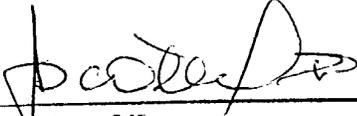
Pioneer Surgical Technologies

SDB Cerclage System Device

Indications for Use

The SDB Cerclage System devices will be offered in two sizes of cable constructs. The large cable construct shall be indicated for general orthopedic trauma surgery involving the following: olecranon, patella, femur (including periprosthetic fractures), pelvic, acetabular, humeral and ankle fractures; acromioclavicular dislocations; prophylactic banding during total joint procedures; and temporary reduction during ORIF (Open Reduction Internal Fixation) procedures. The small cable size shall be contraindicated for use in the femur ORIF and prophylactic banding during total joint procedures. These devices are intended as single use items.

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____ K992616