DEC 19 1997

5. **510(K) Summary**

K974016

Pioneer Laboratories
510(K) Notification Summary
For
Cerclage Cable with Hex Button

Administrative Information

Manufacturer Identification and Sponsor:

Pioneer Laboratories
375 River Park Circle
Marquette, MI 49855-1781
Telephone: 906-226-9909
FAX: 906-226-9932

Official Contact:

Burns Severson
Vice President, Regulatory Affairs/Quality Assurance

Date Prepared:

Device Identification

Proprietary Name:
Cerclage Cable with Hex Button

Common Name
Plate, Fixation, Bone

Classification Name and Reference:
Cerclage, Bone fixation
Regulation Number: CFR 888.3010
Classification Number: 87JDQII

Plate, Fixation, Bone
Regulation Number: CFR 888.3030
Classification Number: 87JDQII

Devices on which substantial equivalence is claimed:

Device Description

The Cerclage with Hex Button is a cerclage cable and a button device that links the cable and bone screw together . The button is positioned in the hex of a bone screw. The cerclage cable is passed through the button and around the bone. The cerclage is crimped to lock the cable in place.

Intended Use

The Cerclage Cable with Hex Button device is indicated for use where wire or cable is used in conjunction with bone screws and/or plating. The system is designed to provide increased compression as compared to only a screw and/or plate in situations where there is inadequate bone stock, multiple fractures or butterfly fragments. The Cerclage Cable with Hex Button device is intended for long bone fractures and is to be used with commercially available bone screws of the same general material type as the plate.

Technological Characteristic Compared to Predicate Device

All the devices use cables, crimps, and a bone plate as a system used for long bone fracture fixation. Each system uses a tensioner and crimp to apply compression, and lock the cable. Each system has a stabilizing feature that limits longitudinal movement of the cable. The Dall-Miles Broad Bone Plate device places the rectangular crimp and cable over the bone plate. The Pioneer Laboratories Bone Plate with Cerclage Cable device has the crimp internal to the plate. The Bone Plate with Cable device has the oval crimp adjacent to the plate with the cable passing through a hole in the plate.

The Cerclage with Hex Button has a cerclage adjacent to the plate with the cable passing through a hole in the hex button that is positioned in the hex of the plate screw.

Performance Data

The Cerclage Cable with Hex Button device was predicated on the use of the Pioneer Laboratories Bone Plate with Cerclage Cable and Bone Plate with Cerclage Cable Device. The static yield loading values indicated that the Cerclage Cable with Hex Button device is equivalent to the values of the three predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

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

Re: K974016
Cerclage Cable with Hex Button
Regulatory Class: II
Product Code: JDQ
Dated: October 16, 1997
Received: October 22, 1997

Dear Mr. Severson:

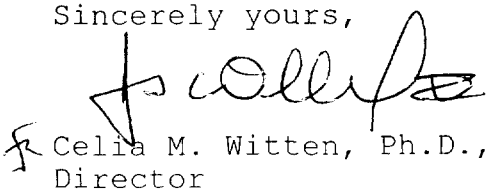
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Pioneer Laboratories

Cerclage Cable with Hex Button Device

Indications for Use

The Cerclage Cable with Hex Button device is indicated for use where wire, cable, or band cerclage is used in combination with plates. The Cerclage Cable with Hex Button device is intended for long bone fractures and is to be used with commercially available bone screws of the same general material type as the plate.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974016