5. 510(K) Summary

Pioneer Laboratories
SEP 10 1997 510(K) Notification Summary
For
Bone Plate with Cables

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: 6/9/97

Device Identification

Proprietary Name:
Bone Plate with Cables

Common Name
Bone Plate

Classification Name and Reference:
Plate, Fixation, Bone:
Regulation Number: CFR 888.3030
Classification Number: 87 HRS
Cerclage, Bone Fixation:
Regulation Number: CFR 888.3010
Classification Number: 87 JDQ II

Devices on which substantial equivalence is claimed:
Dall-Miles Cable Grip System, Broad Bone Plate and Pioneer Laboratories Bone Plate with Cerclage Cables.

Device Description

The Bone Plate with Cable's device consists of a bone plate with transverse holes for passage of multifilament cables. A cable is passed through the transverse bone plate hole, and then through a crimp. The crimp is typically positioned adjacent to the plate. The cable is locked into a tensioning device and tightened which applies compression to the plate and bone. The crimp and cable are then crimped with a crimping tool to lock the cable in place. Excess cable is cut and removed. Additional cables of the same system type maybe applied as required.

Intended Use

The Bone Plate with Cable's device is indicated for use where wire, cable, or band cerclage is used in combination with bone plates. The system is designed to provide increased compression as compared to only a bone plate in situations where there is inadequate bone stock, multiple fractures or butterfly fragments. The Bone Plate with Cable's 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 bone 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. The Dall-Miles Broad Bone Plate device places the rectangular crimp and cable over the bone plate. The Pioneer Laboratories Bone Plate with Cerclage Cables device has the crimp internal to the plate. The Bone Plate with Cable's device has the oval crimp adjacent to the plate with the cable passing through a hole in the plate.

Performance Data

The Bone Plate with Cable's device was predicated on the use of stainless steel wire, Dall-Miles Broad Bone Plate, and the Pioneer Laboratories Bone Plate with Cerclage Cables. Based on tests of each of the systems the Bone Plate with Cable's device and the Pioneer Laboratories Bone Plate with Cerclage Cables exceed the loading values for wire systems. The loading values indicated that the Bone Plate with Cable's device is equivalent to the values of the Pioneer Laboratories Bone Plate with Cerclage Cable's system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1997

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

Re: K972223
Trade Name: Bone Plate with Cable's Device
Regulatory Class: II
Product Codes: HRS and JDQ
Dated: August 19, 1997
Received: August 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 requirements, 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,

for 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

Bone Plate with Cables Device

Indications for Use

The Bone Plate with Cable's device is indicated for use where wire, cable, or band cerclage is used in combination with bone plates. The Bone Plate with Cable's 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 bone plate.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972223