

5. 510(K) Summary

K980690

**Pioneer Laboratories
510(K) Notification Summary
For
Cable Screw with Integral Crimp**

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: 7/22/97

Device Identification

Proprietary:

Pioneer Laboratories Cable Screw with Integral Crimp

Common Names:

Screw, Fixation, Bone
Cerclage Cable

Classification Name and Reference:

In the code of Federal Regulations, Volume 21, FDA identified bone screws, fixation as Class II devices.

Regulation Number: 888.3040

Classification Number: 87HWC

Cerclage, Bone Fixation

Regulation Number: 888.3010

Classification Number: 87JDQ

Class II



MAY 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Burns Severson
Senior Vice President
Pioneer Laboratories, Inc.
375 River Park Circle
Marquette, Michigan 49855

Re: K980690
Cable Screw with Integral Crimp
Regulatory Class: II
Product Code: JDQ and JWC
Dated: February 20, 1998
Received: February 23, 1998

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.

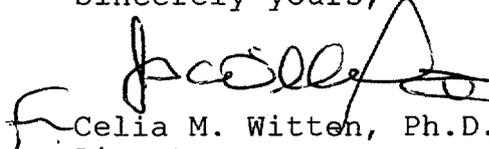
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

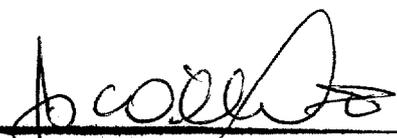
Pioneer Laboratories

Cable Screw with Integral Crimp

Indications for Use

The Cable Screw with Integral Crimp is indicated where a fracture may not be securely held by either a screw or a cerclage cable alone. The device can be used in conjunction with plating:

- humeral fractures
- medial malleolus fractures
- butterfly fractures requiring interfragmentary fixation with cerclage cabling
- femur fractures
- pelvic fractures
- forearm shaft fractures
- patellar fractures
- olecranon fractures
- proximal tibial and tibial shaft fractures



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980690

Prescription Use X
(Per 21 CFR 801.109)