

K992617

***Pioneer Laboratories***

***Hex Button Device***

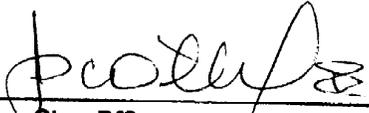
***Indications for Use***

The Hex Button device is indicated for fractures that may not be securely held by either a screw or a cerclage device alone.

The Hex Button device is intended for use where wire, cable, or band cerclage is used in combination with bone screws and/or plates, of the same material type, to provide internal fixation of fractured bone.

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

X

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number \_\_\_\_\_

K992617

OCT 27 1999

K992617

V. 510(K) SUMMARY

***Pioneer Laboratories  
510(K) Notification Summary  
For  
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:** August 3, 1999

**Device Identification**

**Proprietary Name:** Hex Button

**Common Name:** Washer, Bolt, Nut, Orthopedic

**Classification Name and Reference:** Washer, Bolt, Nut, Orthopedic

**Regulation Number:** CFR 888.3030

**Classification Number:** 87HTN

**Device Class:** II

**Devices on Which Substantial Equivalence is Claimed:**

Cerclage Cable with Hex Button Device (K974016)

**Device Description**

The Hex Button is a device that is used with a cerclage device and bone screws. The Hex Button device links the cable and bone screw together. The button is positioned in the v.

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

hex recess of a bone screw. The cerclage cable is passed through the button and around the bone, after which the cerclage device is crimped to lock the cable in place.

**Intended Use**

The Hex Button device is indicated for use where wire or cable is used in conjunction with bone screws and/or plating. The Hex Button device is intended for use where wire, cable, or band cerclage is used in combination with bone screws and/or plates, of the same material type, to provide internal fixation of fractured bone. 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

**Technological Characteristic Compared to Predicate Device**

The Hex Button device is the same button used in the predicate Cerclage cable with Hex Button device (K974016). For both devices, a cerclaging device is passed through the hole in the Hex Button after the button is positioned in the hex recess of a seated bone screw.

**Performance Data**

The Hex Button device was predicated on the use of the Cerclage cable with Hex Button device (K974016). The Cerclage cable with Hex Button device (K974016) was tested in static yield and crevice corrosion fatigue. In both tests, the cerclage cable was the failure mode with the Hex Button showing little if no wear. In no test cases did the Hex Button fail.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 27 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K992617  
Trade Name: Hex Button  
Regulatory Class: II  
Product Code: HTN  
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.

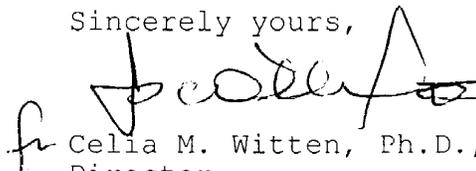
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Burns O. Severson

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