

K981967

JUL 17 1998



CORPORATE HEADQUARTERS

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**Sponsor:** Arthrotek  
Airport Industrial Park  
Warsaw, Indiana 46580

**Proprietary Names:** WasherLoc™ Screw System  
Ligament Screw System  
No-Profile™ Bi-Cortical Screw System  
Channel Ligament Clamp  
Heckman™ Screw System

**Common or Usual Name:** Soft tissue fixation screws

**Classification Name:** Single/multiple component metallic bone fixation appliances and accessories (21 C.F.R. §888.3030)

**Device Classification:** Class II

**Device Product Code:** 87MBI - Fastener, nondegradable, soft tissue

**Intended Use:** Soft tissue fixation to bone, specifically during ligament reconstructive procedures.

**Device Description:** Various style titanium alloy and stainless steel screws and washers. Screw diameters range from 3.5mm to 6.5mm and 10mm to 60mm in length. Washers have posts or spikes to engage the bone.

**Substantially Equivalent Devices:**

Cancellous Fixation Screw & Washer (Concept, Inc.)	K871037
(now marketed by Linvatec)	
MLI Soft Tissue Screw & Washer (Medicine Lodge, Inc.)	K962194
(now marketed by Innovasive)	
SMo Bone Screws (OEC)	Preamendment

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P.O. Box 587  
Warsaw, IN 46581-0587

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219.267.8137

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JUL 17 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
Biomet Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K981967  
Trade Name: WasherLoc™, Ligament Washer, Lo-Profile™,  
Heckman™, and Channel Ligament Screw Systems  
Regulatory Class: II  
Product Codes: MBI and HWC  
Dated: June 2, 1998  
Received: June 4, 1998

Dear Ms. Beres:

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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

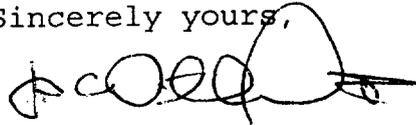
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

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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,



f 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

510(k) Number (if known): K991967

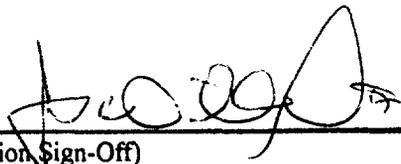
Device Name: Soft Tissue Fixation Screws

Indications For Use:

Soft tissue fixation to bone, specifically during ligament reconstructive procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991967

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_