

4/29/99

K991135

**Exhibit I**

**510(k) Summary  
Soft Tissue Suture Washer**

---

DePuy, Inc.  
700 Orthopaedic Drive  
Warsaw, IN 46581

**A. Contact Person:**

Janet G. Johnson, RAC  
Senior Regulatory Associate  
(219) 372-7484

**B. Device Information:**

<b>Proprietary Name:</b>	Soft Tissue Suture Washer
<b>Common Name:</b>	Suture Washer
<b>Classification Name:</b>	Single/multiple component metallic bone fixation appliances and accessories.
<b>Regulatory Class:</b>	Class II, per 21 §CFR 888.3030
<b>Product Code:</b>	87 HTN

**C. Indications for Use:**

To provide fixation to bone of the tibial and/or femoral end of a bone-patellar tendon-bone graft or other soft tissue graft material used to reconstruct the ACL and/or PCL in an intra-articular procedure of the knee.

**D. Device Description:**

The Soft Tissue Suture Washer is a titanium alloy (Ti-6Al-4V) three-hole suture washer that is intended to be used with cancellous or cortical bone screws. This suture washer is designed to prevent migration of screw head into the bone and provide an anchoring site for sutures.

**E. Substantial Equivalence:**

The Soft Tissue Suture Washer is substantially equivalent in terms of intended use, materials, design, manufacturing and packaging to the current DePuy OrthoTech Soft Tissues Suture Washer (K910229).

The determination of substantial equivalence for this device was based on a detailed device description, and conformance with voluntary performance standard ASTM F136.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 29 1999

Janet G. Johnson, RAC  
Senior Regulatory Associate  
DePuy Orthopaedics, Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Re: K991135  
Trade Name: Soft Tissue Suture Washer  
Regulatory Class: II  
Product Code: HTN  
Dated: April 1, 1999  
Received: April 5, 1999

Dear Ms. Johnson:

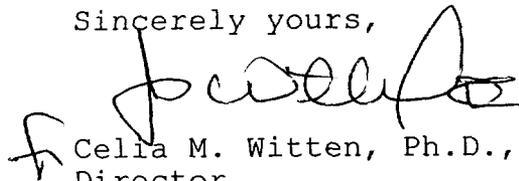
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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)

K991135

Device Name

Soft Tissue Suture Washer

**Indications for Use**

To provide fixation to bone of the tibial and/or femoral end of a bone-patellar tendon-bone graft or other soft tissue graft material used to reconstruct the ACL and/or PCL in an intra-articular procedure of the knee.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K991135

Prescription Use X  
(Per 21 CFR §801.109)

OR

Over-the-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)