

FEB 1 1999

**510(k) SUMMARY**  
**Implex Screw and Washer System**

**Submitter Name:** Implex Corp.

**Submitter Address:** 80 Commerce Drive  
Allendale, New Jersey 07401-1600

**Contact Person:** John Schalago, RAC or Robert Poggie, Ph.D.

**Phone Number:** (201) 818-1800

**Fax Number:** (201) 818-0567

**Date Prepared:** January 27, 1999

**Device Trade Name:** Implex Screw and Washer System

**Device Common Name:** Washer, bolt, nut

**Classification Number and Name:** 21 CFR § 878.3030

**Substantial Equivalence:** The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

**Device Description:** The Implex Screw and Washer System consists of the Implex Continuum Bone Screw configured with a Hedrocel<sup>®</sup>/CP titanium Washer. The Implex Continuum Bone Screw has a 5 mm diameter and is offered in lengths from 15 to 65 mm, in 5 mm increments. The Washer is offered in two versions, Washer-A and Washer-B. Washer-A has a flat tissue-contacting surface and Washer-B has a flat tissue-contacting surface with recessed grooves. Both versions are round, and offered in three outer diameters, 14 mm, 17 mm, and 20 mm.

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**510(k) Summary of Safety and Effectiveness (continued)**

- Indications for Use:** The Implex Screw and Washer System is indicated for use in the attachment of ligaments, tendons and other soft tissue to bone.
- Device Technological Characteristics and Comparison to Predicate Device:** The Hedrocel™ Screw and Washer System has the same intended use and indications for use, and is offered in equivalent geometries and sizes as the predicate devices.
- Performance Data:** Performance data provided in MAF#920 demonstrates that material and structural properties of the washer component of the Implex Screw and Washer System are suitable for the intended use of the device. The screw is a currently legally marketed bone screw. Mechanical testing demonstrating the strength of the CP Titanium/Hedrocel™ interface is included in this 510(k) Premarket Notification.
- Predicate Device Information:** The predicate device cited in this premarket notification to support a determination of substantial equivalence are the Implex Continuum™ Bone Screw, the MDLI Soft Tissue Screw and Washer System, and the Mitek Screw and Washer System.
- Conclusion:** The Implex Screw and Washer System is substantially equivalent to the identified predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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John A. Schalago, RAC  
Regulatory Affairs Manager  
Implex Corporation  
80 Commerce Drive  
Allendale, New Jersey 07401-1600

Re: K982751  
Trade Name: Implex Corporation Screw and Washer System  
Regulatory Class: II  
Product Codes: MBI and HWC  
Dated: November 3, 1998  
Received: November 4, 1998

Dear Mr. Schalago:

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.

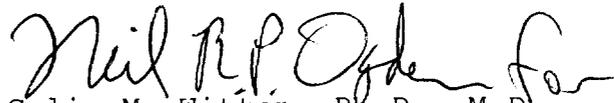
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

