

APR 29 1998

510(k) Summary

Proprietary Name: Howmedica® and Howmedica® Leibinger Bone Screw Washers
Common Name: Washers
Classification Name & Reference: Smooth or threaded metallic bone fixation fastener
21 CFR 888.3040
Proposed Regulatory Class: II
Device Product Code: HWC

For information contact: Sean Luland
Regulatory Affairs Associate
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Phone: (201) 507-7437
Fax: (201) 507-6870

The Howmedica® and Howmedica® Leibinger Bone Screw Washers consist of sizes ranging from .8 mm internal diameter to 3.5 mm internal diameter. The washers are used in conjunction with screws, of like or similar material, currently available in Luhr® and Leibinger®-Luhr® plating systems, which were cleared under various 510(k) notifications (K761228, K854886, K862482, K862534, K882454, K901941, K913355, K923861, K935448, K950595, K951415, K961485, K961497, K963739, K963740, K970912,) and any future styles of Howmedica® and Howmedica Leibinger® screws found substantially equivalent.

The washers are intended to be used to provide additional surface area contact between the screw head and bone surface, when used in combination with bone screws for small bone reconstruction of the mandible, hand, foot and the midfacial skeleton where there exists a condition of a thin cortex or osteoporotic bone.

The substantial equivalence of these components is based on an equivalence in intended use, materials, design, and operational principles to Howmedica's Large Cancellous Washer, Vitallium Washer, ICS Mini and Small Fragment Set Washer and Synthes® Mini Fragment Implant Set Washer and Schuhli Washer.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1998

Mr. Sean Luland
Regulatory Affairs Associate
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K980364
Trade Name: Bone Screw Washers
Regulatory Class: II
Product Code: HWC
Dated: January 28, 1998
Received: January 29, 1998

Dear Mr. Luland:

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.

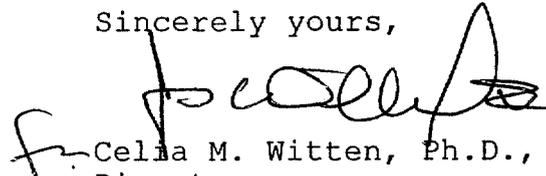
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Sean Luland

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

Indications for Use

510(k) Number (if known): K 980364

Device Name: The Howmedica® and Howmedica® Leibinger Bone Screw Washers

Indications for Use:

The washers are intended to be used to provide additional surface area contact between the screw head and bone surface, when used in combination with bone screws for small bone reconstruction of the mandible, hand, foot and the midfacial skeleton where there exists a condition of a thin cortex or osteoporotic bone.

(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

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

[Signature] (Optional Format 1-2-96)
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980364