

JUN 18 1998

K974843

510(k) Summary

Device: Small Duracon Stabilizer Insert and Screw - Design Modification

This 510(k) describes a modification to the design of the locking screw of the small Duracon Stabilizer insert. The screw length was optimized to increase the engagement into the baseplate. Fatigue testing was presented to support this design optimization. This design change is being undertaken to address laboratory breakage of the small Duracon stabilizer locking screw under severe loading conditions.

There is no modification in the intended use of the product. The small Duracon Stabilizer Tibial Insert is intended to be used with Howmedica Universal tibial baseplates in cemented primary or revision total knee arthroplasty. This insert is intended to be used specifically when the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The intercondylar post of the insert is intended to limit anterior-posterior motion, as does the posterior cruciate ligament in the intact knee.

This design is not intended to provide an absolute substitution for either collateral ligament. Therefore, the collateral ligaments should be intact, or there should be adequate overall capsular ligamentous stability. As previously stated, this product is intended to be used as part of a cemented total knee system.

The design of the small tibial insert and Vitallium support bracket are unchanged. The only design modification is that the locking screw has been lengthened.

There has been no change in the materials used in the fabrication of the inserts and screws. The tibial insert is fabricated from Ultra-high Molecular Weight Polyethylene which conforms to ASTM specification F-648. The support bracket is manufactured from cast cobalt-chromium-molybdenum (Vitallium®) alloy which conforms to ASTM specification F-75. The locking screw is manufactured from wrought Vitallium alloy which conforms to ASTM F-799.

In order to determine that the modified locking screw would provide adequate fixation for the insert to the baseplate, the following testing was performed:

Six small Duracon stabilizer tibial inserts were assembled to Universal tibial baseplates using the longer locking screw. The screws were torqued to 60 in-lbs as described in the surgical technique. Dynamic fatigue testing was performed with the load applied by a Duracon femoral component. The load applied mimicked level walking conditions. All six components survived ten million cycles of loading.

To further evaluate the new length of locking screw, multi-axis dynamic testing of the small insert-baseplate-screw assembly was undertaken. This testing applies severe loads to the locking mechanism, with an axial compressive load, anterior-posterior shear, internal/external rotation and bending moment applied. This testing was performed in a saline environment. Because of the severe loading conditions of the test, fewer samples were tested. All samples survived this severe testing to one million cycles without failure.

A label will be applied to these components to instruct the user to tighten the locking screw to 60-80 in. lbs. The tightening torque for the modified screw is 60-80 in. lbs.

Howmedica believes that the information presented in this premarket notification support a finding of substantial equivalence for the modified small Duracon tibial insert-screw assembly .

For further information please contact: Margaret F. Crowe
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1998

Mr. John Dichiaro
Director, Regulatory Affairs and Public Policy
Howmedica, Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K974843
Trade Name: Duracon® Small Stabilizer Tibial Insert
Regulatory Class: II
Product Code: JWH
Dated: April 9, 1998
Received: April 10, 1998

Dear Mr. Dichiaro:

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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial insert available is the nominal "9mm" sized insert, which has a minimum polyethylene thickness under the condyles of 6.19mm.
2. This device may not be labeled or promoted for non-cemented use.
3. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

4. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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.

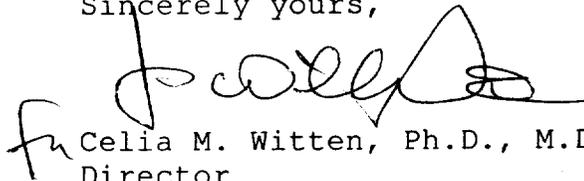
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

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

Page 3 - Mr. John Dichiaro

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): K974843

Device Name: Small Duracon® Stabilizer Insert and Screw

Indications for Use:

The small Duracon® Stabilizer Tibial Insert is intended to be used with Howmedica Universal tibial baseplates in cemented primary or revision total knee arthroplasty. This insert is intended to be used specifically when the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The intercondylar post of the insert is intended to limit anterior-posterior motion, as does the posterior cruciate ligament in the intact knee.

This design is not intended to provide an absolute substitution for either collateral ligament. Therefore, the collateral ligaments should be intact, or there should be adequate overall capsular ligamentous stability.

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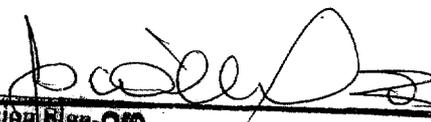
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974843