

MAY 22 1997

K970758

510(k) Summary

**Device: Duracon® Extra-Small Stabilizer Tibial Insert and Baseplate**

The Duracon® Extra-Small Stabilizer Tibial Insert and Baseplate are intended to be used with previously released Duracon® femoral and patellar components as a total knee system in primary or revision cemented total knee arthroplasty. These components are specifically intended to be used in situations where the posterior cruciate ligament is not intact, not present, or cannot be repaired. The collateral ligaments should be intact, or repaired so that adequate mediolateral stability is present. These components are intended to be implanted using bone cement in small boned, skeletally mature individuals.

These components are substantially equivalent to other legally marketed devices. These devices include: 1) Duracon® Stabilizer Tibial Insert (Howmedica - K932070) and 2) Duracon® Universal Baseplate (Howmedica - K915512). This substantial equivalence is based on similarities in intended use, design, materials, and surgical placement.

Testing of these extra-small components was presented in accordance with the FDA Draft Guidance on Testing Semi-Constrained Total Knee Replacements.

For information contact: Margaret F. Crowe  
Manager, Regulatory Affairs  
Howmedica Inc.  
359 Veterans Boulevard  
Rutherford, NJ 07070  
(201) 507-7431 - Phone  
(201) 507-6870 - Fax



MAY 22 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Margaret F. Crowe  
Manager, Regulatory Affairs  
Howmedica Inc.  
Pfizer Hospital Products Group  
359 Veterans Boulevard  
Rutherford, New Jersey 07070-2584

Re: K970758  
Duracon® Extra-Small Stabilizer  
Tibial Insert and Baseplate  
Regulatory Class: II  
Product Code: JWH  
Dated: February 28, 1997  
Received: March 3, 1997

Dear Ms. Crowe:

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 6.0mm.
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.

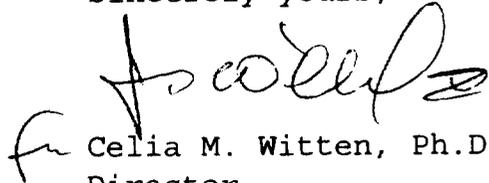
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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,

A handwritten signature in cursive script, appearing to read "Celia M. Witten".

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):

Device Name: Duracon® Extra-Small Stabilizer Tibial Insert and Baseplate

Indications for Use:

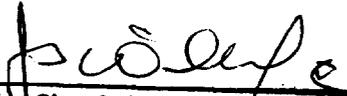
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   x    
(Per 21 CFR 801.109)

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

 (Optional Format 1-2-96)  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number   16970759