K973164

510(k) Summary

NOV 20 1997

Device: Howmedica® Total Stabilizer Knee Components

The Howmedica® Total Stabilizer Knee Components (Stabilizer femoral component, stabilizer tibial insert, modular offset adaptor, femoral/tibial stem extenders and tibial wedges) are intended to be used along with previously released Duracon® tibial and patellar components as a total knee system in primary or revision cemented total knee arthroplasty. This total knee system is intended to be used to relieve pain and instability of the knee joint as a result of non-inflammatory joint disease, inflammatory joint disease, trauma, or failed previous prosthesis.

The Howmedica® Total Stabilizer femoral component and tibial insert components are specifically intended to be used when the cruciate ligaments are absent, inadequate, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to the absence of the posterior cruciate ligament and/or patella. The collateral ligaments may or may not be intact. In addition, these components may be used in revision of a failed previous prosthesis where the cruciate ligaments are absent.

The Howmedica® tibial wedges are intended to be used with the Howmedica® Universal tibial baseplate to augment bone loss on the surface of the tibia. Tibial bone loss may be observed in primary or revision total knee arthroplasty.

The Howmedica® Modular Offset Adaptor is intended to be used in situations where a stem extender is being used, and the tibial baseplate or femoral component requires offsetting with respect to the intramedullary canal to allow optimal coverage of the prepared bone surfaces.

The Howmedica® Stem Extenders are intended to be used with Duracon®/ Kinemax® femoral/tibial components in primary/revision total knee arthroplasty where additional stability is required.

The Howmedica® Total Stabilizer Knee Components are intended to be implanted using bone cement.

These components are substantially equivalent to other legally marketed devices. Comparisons to these components were presented, as well as testing included in the FDA Total Knee Guidance Document.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1997

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

Re: K973164
Howmedica Total Stabilizer Knee Components
Regulatory Class: II
Product Code: JWH
Dated: August 22, 1997
Received: August 25, 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 "11mm" sized insert, which has a minimum polyethylene thickness under the condyles of 8.6mm.

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.

3. 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,

for 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: K973164

Device Name: Howmedica Total Stabilizer Knee Components

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The Howmedica Total Stabilizer Knee Components are intended to be implanted using bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973164