

## 510(k) Summary

JUL - 8 1997

Device: Kinematic® All-Polyethylene Patella with Three Pegs

The Kinematic® All-Polyethylene Patella with Three Pegs is intended to be used with the femoral and tibial components of the Kinematic® and Kinematic® II total knee systems, and the distal femoral component of the Howmedica Modular Replacement System in primary and/or revision total knee arthroplasty. This component is intended to resurface the articular surface of the patella. It is intended to be implanted with bone cement.

The Kinematic® All-Polyethylene Patella with Three Pegs is available in three sizes: small, medium, and large. This component has a rounded, dome articular surface that is intended to mate with the intercondylar recess of the above-referenced femoral components. The articular surface of the subject device is identical to the articular surface of the previously cleared Kinematic® Patella.

The undersurface design of the Kinematic® All Polyethylene Patella with Three Pegs has a triangular cement recess with three straight pegs. This undersurface design is identical to the Duracon® All Polyethylene Patella II undersurface. The existing Kinematic® Patella has a central keel with fixation holes. This undersurface is being modified to three pegs to allow common instrumentation to be used throughout Howmedica's total knee systems.

The Kinematic® All-Polyethylene Patella with Three Pegs is fabricated from Ultra-High Molecular Weight Polyethylene, which conforms to ASTM specification F-648. The Kinematic® All Polyethylene Patella with Three Pegs will be made available in two versions: one will be sterilized via a room air gamma sterilization method, and the second version will be sterilized via a gamma sterilization method in an inert environment followed by heat treatment.

The Kinematic® All Polyethylene Patella with Three Pegs is substantially equivalent to other legally marketed Howmedica devices: 1) Kinematic® All Poly Patella and 2) Duracon® All Polyethylene Patella II. This substantial equivalence determination is based on similarities in design, materials, intended use and operational principles.

Patello-femoral contact area and lateral subluxation testing of the patella were presented.

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



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

JUL - 8 1997

Re: K971550  
Kinematic All-Polyethylene  
Patella with 3 Pegs  
Regulatory Class: II  
Product Code: JWH  
Dated: April 25, 1997  
Received: April 28, 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. This device may not be labeled or promoted for non-cemented use.
2. 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.

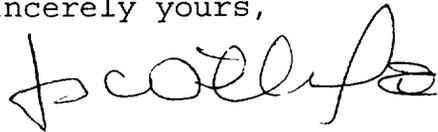
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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 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 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): K971550

Device Name: Kinematic® All-Polyethylene Patella with Three Pegs

Indications for Use:

The Kinematic® All-Polyethylene Patella with Three Pegs is intended to be used with the femoral and tibial components of the Kinematic® and Kinematic® II total knee systems, and the distal femoral component of the Howmedica Modular Replacement System in primary and/or revision total knee arthroplasty. This component is intended to resurface the articular surface of the patella. It is intended to be implanted with bone cement.

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

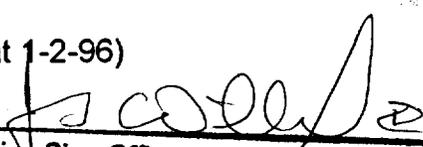
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (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

K971550