K973121

510(k) Summary

NOV 18 1997

Device: Interax® Total Knee System

The Interax® Total Knee System is intended to be used in cemented primary and/or revision total knee arthroplasty procedures in patients who require total knee replacement as a result of non-inflammatory joint disease and all of its variants, inflammatory joint disease, trauma, or failed previous prosthesis. The Interax® system is intended to accommodate the posterior cruciate ligament if it is intact. The collateral ligaments should be intact, or reparable, or there must be adequate capsular support to provide medio-lateral stability. The Interax® Total Knee System is intended to be implanted using bone cement.

The Interax® Total Knee System consists of a variety of components. Each of these components is described below:

1. Femoral Component

   The femoral component is available in left and right configurations, and a range of sizes to match varying patient anatomy. The sizes of the femoral components are grouped into three size ranges.

   The internal aspect of the femoral component incorporates a macrotextured ("diamond") surface for cement bonding. There are cement recesses which help ensure an adequate cement mantle. There is a central stem on the component which has a PMMA plug. This plug can be removed to allow the use of femoral stem extensions (described below).

2. Tibial Baseplate

   The tibial baseplate is neutral (no lefts/rights), and it is available in a range of sizes to match varying patient anatomy. The sizes of the tibial components are grouped into the same three size ranges as the femoral component.

   The superior surface of the tibial baseplate has a central dovetail, an anterior abutment, and medial and lateral tabs. These features form the baseplate portion of the insert-baseplate locking mechanism. There is a hole on the superior aspect of the baseplate that accepts a screw to secure tibial stem extensions.

   The undersurface of the tibial baseplate has a short central stem with a PMMA plug which can be removed to allow the optional use of stem extenders (described below). There are fins coming off the stem which run at an angle toward the posterior aspect of the baseplate. These fins provide rotational stability. The undersurface of the baseplate is macrotextured ("diamond") to enhance cement bonding.

3. Tibial Inserts

The Interax® Tibial Inserts are available in two styles: a standard condylar design, and a high conformity condylar design. The Interax® tibial inserts are available in two halves. This allows the surgeon to evaluate the medial and lateral compartments of the knee individually. The surgeon can utilize different insert thicknesses of up to 2mm between the medial and lateral side of the tibial plateau to compensate for the soft tissue tension observed in the joint.

Both the standard condylar and high conformity condylar inserts are available in four size ranges to accommodate the choice of one size up and one size down interchangeability. The inserts are available in a variety of thicknesses to accomodate varying patient anatomy. The minimum polyethylene thickness of these inserts is 6mm.

4. All Polyethylene Patellar Components

There are two styles of all polyethylene patellar components: a resurfacing design and an inset design. Both styles are available in four sizes. Because the radius at the base of the patellar groove of the femoral component remains constant for all sizes of femoral component, all sizes of patellar components can be used with all sizes of femoral components.

5. Femoral Extension Stems

The Femoral Stem Extensions are rod shaped with a rounded end and grooves to enhance cement bonding, and to enhance stability. These stem extensions are screwed into the central stem on the femoral component. These stems are available in varying lengths.

6. Tibial Extension Stems

The tibial extension stems are available in two styles: a cylindrical extension stem, and a cruciform extension stem. The cylindrical stems are rod shaped with rounded ends and grooves to enhance cement bonding and to provide some rotational stability. The cruciform style is a cruciform keel shape that provides rotational stability, but is less invasive. Both styles of extension stems mate with the stem of the tibial baseplate via a Morse taper connection that is augmented by a locking screw.

7. Tibial Wedges

The tibial wedges are designed to address bony defects on the medial or lateral aspect of the proximal tibia. These wedges are angled 10°, and are available in varying sizes to match the undersurface of the tibial baseplates. There is a groove in the wedge to allow it to mate with the fins on the undersurface of the tibial baseplate. This wedge is cemented to the baseplate, and then the wedge-baseplate combination is cemented into the proximal tibia.

The Interax® Total Knee System is substantially equivalent to other legally marketed devices: Duracon® Total Knee System (Howmedica) and Kinemax® Plus Total Knee System (Howmedica). Testing was presented in accordance with the FDA Total Knee Guidance Document.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 18 1997

Re: K973121
Interax® Total Knee System
Regulatory Class: II
Product Code: JWH
Dated: August 19, 1997
Received: August 20, 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). 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 (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. 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,

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

K973121

510(k) Number (if known):

Device Name: Interax® Total Knee System

Indications for Use:

The Interax® Total Knee System is intended to be used in cemented primary and/or revision total knee arthroplasty procedures in patients who require total knee replacement as a result of non-inflammatory joint disease and all of its variants, inflammatory joint disease, trauma, or failed previous prosthesis. The Interax® system is intended to accommodate the posterior cruciate ligament if it is intact. The collateral ligaments should be intact, or reparable, or there must be adequate capsular support to provide medio-lateral stability. The Interax® Total Knee System is 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 K973121