K030446
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BIOMET

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

MAR 0 6 2003

Contact Person: Tracy J. Bickel
(574) 267-6639

Proprietary Name: Repicci™ Locked Keel Tibial Bearing

Common Name: Unicompartmental Knee Tibial Component

Classification Name: Prosthesis, Knee, Femorotibial, semi-constrained, cemented, metal/polymer (21 CFR 888.350)

Substantially Equivalent Devices: Worland Unicondylar All Poly Tibial Bearing – K011795

Device Description: The Repicci II® Unicondylar Knee System consists of a femoral and tibial component. The Repicci™ tibial bearing is used with the Repicci™ femoral components (K971938).

The all polyethylene tibial components are anatomical in geometry with right and left medial/lateral allocations. Located on the inferior surface of the implant is a face with fixation holes and a keel.

Intended Use: Partial replacement of articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

The devices covered in this 510(k) are intended to be used with Repicci™ Femoral Components.

The device is a single use implant intended for implantation with bone cement.

Summary of Technologies: The Repicci™ Locked Keel Tibial components materials, design, sizing, and indications are similar to, or identical to the predicate devices. This submission modifies the keel on the inferior surface of the implant and removes the waffle pattern.

Non-Clinical Testing: An engineering justification determined that the Repicci™ Locked Keel tibial components presented no new risks and were; therefore, substantially equivalent to the predicate device.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 6 2003

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K030446
Trade/Device Name: Repicci™ Locked Keel Tibial Bearing
Regulation Number: 21 CFR 888.3530
Regulation Names: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: February 7, 2003
Received: February 11, 2003

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

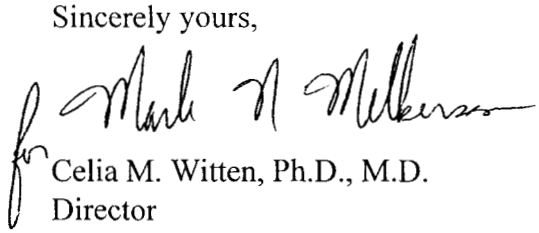
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030446
Device Name: **Repicci™ Unicondylar Tibial Bearings**
Indications for Use:

Partial replacement of articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

The devices covered in this 510(k) are intended to be used with Repicci® Femoral Components.

The device is a single use implant intended for implantation with bone cement.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030446

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)