JAN 5 2006

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Repicci II® Onlay Unicompartmental Tibial Component

Common or Usual Name: Tibial component for Uni-Condylar knee replacement

Classification Name: Knee joint, femoratibial metal/polymer semi-constrained cemented prosthesis (21 CRF 888.3530, 87 HRY)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Repicci II® Unicondylar Knee (Biomet-K971938, K980665)
- DePuy Preservation™ Unicondylar Knee Prosthesis (DePuy Orthopedics, Inc. - K010810)
- ADVANCE® Unicondylar Knee System (Wright Medical Technology, Inc.-K012591)

Device Description: The Repicci II® Onlay Tibial Component is an all-polyethylene unicondylar tibial component with four inferior fixation pegs. The inferior surface has macro grid (waffle) texture as well as four undercut pegs for cement fixation. Components in five profiles and four thicknesses are available.

Intended Use: Partial replacement of the 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. This device is intended for cemented application only.

Summary of Technologies: The technological characteristics (materials, design, sizing and indications) of the Repicci II® Onlay Tibial Component are similar to or identical to the predicate devices or other previously cleared devices.

Non-Clinical Testing: Mechanical testing provided

Clinical Testing: None provided.

Prepared: January 4, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 5 2006

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P. O. Box 587
Warsaw, Indiana 46581-0578

Re: K053299
Trade/Device Name: Repicci II Onlay Unicompartmental Tibial Component
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: November 23, 2005
Received: November 25, 2005

Dear Ms. Beres:

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Repicci II® Onlay Unicompartmental Tibial Component

Indications For Use: Partial replacement of the 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.

This device is intended for cemented application only.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053299