K094017 (1/2)

510 (k) Summary
For the OMNI life science Apex Knee System Tibial Baseplate Augment

MAR - 5 2010

Submitter	OMNI life science, Inc. 50 O'Connell Way #10 E. Taunton, MA 02718
Contact Person	Robert Zoletti OMNI life science, Inc. 50 O'Connell Way #10 E. Taunton, MA 02718 Tel: 774-226-1845 Fax: 508-822-6030 Email: rzoletti@omnils.com
Preparation Date	February 26, 2010
Common Name	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Trade Name	Apex Knee System Tibial Baseplate Augment
Classification Name	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Classification Panel	Orthopedic (OR)
Regulatory Class	Class II per 21 CFR 888.3560
Product Code	JWH
Legally Marketed Predicate Device(s)	Apex Knee System K060192 Tibial Spacer for the Natural Knee K031183
Device Description	The Augments are used as optional spacers and are cemented below the Tibial Tray using PMMA bone cement. The Tibial Baseplate Augment is available in the following Sizes: • Size 1 x 8mm • Size 2 x 8mm • Size 3 x 8mm • Size 4 x 8mm • Size 5 x 8mm
Indications for Use	The Apex Knee System Tibial Baseplate Augment is intended for use with the Apex Knee System as a primary or revision total knee replacement. This knee replacement system is intended for cemented fixation and single use implantation. This prosthesis may be used for the following conditions, as appropriate: • Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;

- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed.

Technological Characteristics	The Augments are manufactured from Ti-6Al-4V and designed for use with the Apex Knee System cleared in K060192.
Substantial Equivalence Comparison	Performance testing, design comparisons, and functional analysis conducted on the Augments demonstrate that they are equivalent to the predicate devices.
Clinical and Non-Clinical Data	The Apex Tibial Baseplate Augments were bench tested to assure usability and function.
Packaging and Sterilization	Packaged Sterile EO Sterilized, SAL 10^{-6} Shelf life is 5 years from date of manufacture

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 5 2010

OMNI Life Science, Inc.
% Mr. Robert Zoletti
50 O'Connell Way #10
East Taunton, Massachusetts 02718

Re: K094017
Trade/Device Name: Apex Knee System Tibial Baseplate Augment
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemoraltibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: February 12, 2010
Received: February 16, 2010

Dear Mr. Zoletti:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K094017

Device Name: Apex Knee™ System Cemented Tibial Augment

Indications for Use

The Apex Knee System Tibial Baseplate Augment is intended for use with the Apex Knee System as a primary or revision total knee replacement. This knee replacement system is intended for cemented fixation and single use implantation. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K094017