K101994 (1/3)

SEP 28 2010

510(k) Summary

Apex Knee ™ Modular Tibia System 22 September, 2010

Submitter OMNI life science, Inc.
50 O'Connell Way
E. Taunton MA 02718

Contact Radhika Pondicherry
Regulatory Affairs
774-226-1852
(508) 822-6030 (fax)

Preparation Date 22 September 2010

Device Nam

Trade Name	Apex Knee ™ Modular Tibia System
Common/Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class	Class II per 21 CFR §888.3560
Product Code	JWH, MBH

Legally Marketed Predicate Device(s)

- K060192- Apex Knee System, cleared 15Jul2006
- K094017- Apex Knee System Tibial Baseplate Augment, cleared 05Mar2010
- K080361- Biomet, Regenerex™ Tibial Component, cleared 21April2008

Device Description

The Modular Tibial Baseplate is offered in sizes 1 thru 6 and is a symmetrical design. It is 5mm thick, and accepts Tibial Stems and Augment Blocks on its inferior surface.
Modular Tibia Stems are available from 9-17mm diameter in lengths of 75,100 or 150mm. The stem mates to the Modular Tibial Baseplate via a Morse taper connection, secured by a Locking Bolt.
Modular Tibia Augments are available in, size 1 thru 6. Each Augment is 4mm thick, and may be placed on either the medial or lateral side of the baseplate. They may be stacked up to three high in equal or descending sizes to create either a uniform or stepped lateral profile. Bone cement should not be used between stacked augments. Once stacked the augments must be secured to the tibial tray using a locking bolt of appropriate length to match the height of the augment stack. The Tibial tray (tibial baseplate) - augment assembly is then cemented to the prepared tibia.

Indications for Use

The Apex Knee ™ Modular Tibia System is intended for use as a primary or revision total knee replacement.
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

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.
The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

Predicate Device Comparison

	Apex Knee Modular Tibial (subject device)	Apex Tibial Baseplate Augment (K094017)	Biomet- Regenerex Tibial Component (K080361)
Intended Use			
Intended Use	Primary and revision total knee replacement	Primary and revision total knee replacement	Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved. Correction of varus, valgus, or posttraumatic deformity. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.
Design			
Modular Tibial Baseplate insert locking mechanism	Dovetail rails for engaging the UHMWPE tibial insert with a central threaded hole for receiving the locking bolt	Dovetail rails for engaging the UHMWPE tibial insert with a central threaded hole for receiving the locking bolt	N/A
Modular Tibia Stem, Keel and Cap	**Modular Stem, Keel and Cap**- Attaches to the Tibial Baseplate via a Morse taper connection, secured by a Locking Bolt. Provides rotational stability and a point of fixation for the locking bolt to thread onto.	Monoblock Tibial Baseplate and keel.	Modular press fit stem – taper junction and screw.
Modular Tibia Augments	Symmetrical Augments are stackable and flipable and attach to the bottom of the Tibial Baseplate.	Designed to mate with and be cemented to the Apex Knee System Tibial Baseplate.	N/A
Modular Tibia Augment Bolt	Locking bolt used to secure the attachment of the Tibial Augments to the Tibial Baseplate.	Locking bolt used to attach Tibial Augments, polyethylene insert and Tibial Baseplate. Locking bolt used to	N/A

Insert Retaining Bolt (UHMWPE)	Locking bolt used to secure the attachment of the Insert to the Tibial Baseplate	secure the attachment of the Insert to the Tibial Baseplate	
Modular Tibia Pegs	Attaches to the threaded holes in the bottom of the tibial Baseplate. Modular Peg provides additional rotational stability to the tibial component when the Tibial Augments are not being used.	NA	Modular Tibial Pegs used to stabilize the Tibial Plate on the tibial plateau.
Materials and Standards			
Knee components	ASTM F75-Cobalt chromium- Tibial Baseplate, Tibial Augments ASTM 136- Ti-6Al-4V ELI titanium alloy- Inset locking bolt, Augment locking bolt, Cap, Stem, Keel and Pegs.	ASTM F1537- Wrought cobalt chromium- Tibial Baseplate ASTM 136- Ti-6Al-4V ELI titanium alloy- Tibial Baseplate Augment	CoCrMo alloy- Modular Pegs Titanium Alloy- Modular press fit stem

Non-Clinical Test Summary

The following tests were conducted:

- Fatigue Strength Testing per ASTM F1800-07
- Augment Attachment Strength per ASTM F1814-97AR03
- Fretting Analysis per ASTM F1800-07
- Stem Attachment and Tray/Augment Attachment Strength ASTM F1814-97

All samples tested met the acceptance criteria.

Clinical Test Summary

No clinical studies were performed.

Conclusions

The Apex Knee ™ Modular Tibia System is substantially equivalent to the predicate devices.

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

OMNI Life Science, Inc.
c/o Ms. Radhika Pondicherry
50 O'Connell Way Suite 10
East Taunton, MA 02718

SEP 28 2010

Re: K101994
Trade/Device Name: Apex Knee Modular Tibia System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: July 13, 2010
Received: July 15, 2010

Dear Ms. Pondicherry:

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,

For Peter D Rumm MD
Rumm MD
Dep D.R

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

K101994

SEP 28 2010

510(k) Number: K101994

Device Name: Apex Knee ™ Modular Tibia System

The Apex Knee ™ System is intended for use as a primary or revision total knee replacement. 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.

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only. The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K101994