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510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive P.O. Box 587 Warsaw, IN 46581-0857
Establishment Registration Number	1825034
Name of contact person	Jason Heckaman Regulatory Affairs Project Manager
Phone number	(574) 371-3707
Fax number	(574) 372-1683
Date prepared	July 30, 2014
Name of device	
Trade or proprietary name	Vanguard® 360 OsseoTi™ Tibial Sleeve Augments
Common or usual name	Knee Prosthesis
Classification name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21CFR §888.3565)
Classification panel	Orthopedic
Regulation	21 CFR §888.3565
Product Code(s)	MBH, JWH
Legally marketed device(s) to which equivalence is claimed	K093293 Vanguard 360 Revision Knee System K121149 Vanguard SSK 360 Revision Knee System K072336 Regenerex Porous Titanium Sleeve Augments K102896 Zimmer Trabecular Metal Tibial Cone Augments
Reason for 510(k) submission	The Vanguard 360 OsseoTi Tibial Sleeve Augments are new products that are an addition to the Biomet® Vanguard® 360 Knee Joint System (K093293 and K121149).
Device description	The Vanguard 360 OsseoTi Tibial Sleeve Augments are porous, modular augment sleeves that have been designed to address a wide range of defects in cases of severe bone loss in both primary and revision cases. The subject augments are constructed from a previously cleared materials/additive manufacturing process known as OsseoTi. The OsseoTi process results in a fully integrated part with solid and porous regions. This structure leads to a highly interconnected volume of porosity and promotes biological fixation.

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	The subject OsseoTi Tibial Sleeve Augments mount directly onto the previously cleared Vanguard 360 Tibial Tray boss via Morse tapers. The subject augments are available in half and full sleeve configurations and multiple sizes.
Intended use of the device	The Vanguard 360 OsseoTi Revision Sleeve Tibial Augments are optional components intended to be used with the previously cleared Vanguard 360 Revision Knee System as part of a total knee construct. The subject augments are intended for uncemented biologic fixation.
Indications for use	1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved. 2. Correction of varus, valgus, or posttraumatic deformity. 3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure. The Regenerex femoral augments are indicated for use with the Vanguard Total Knee System. The Regenerex tibial augments are indicated for use with standard and offset Biomet® Tibial Trays. Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok) femoral components, tibial tray components and all polyethylene patellar components are indicated for cemented application only. Regenerex and OsseoTi components are intended only for uncemented biologic fixation application. The Vanguard DA 360 components are not intended for use with the Vanguard PS Open Box Porous Femoral components. **The Vanguard DA 360 components are not approved for sale in the United States.**

Summary of the technological characteristics of the device compared to the predicate

The technological characteristics of the Vanguard 360 OsseoTi Augments are similar to those of predicate systems (K093293/K121149, K072336, K102896) in terms of geometry, design and principle of operation. The subject OsseoTi augments use the same Morse taper for attachment to the previously cleared Vanguard 360 tibial boss as the predicate Vanguard 360 Cruciate Wing augments but with varying taper engagement. The cone shape and sizing of the subject device is similar to the previously cleared Regenerex (K072336) and Zimmer Trabecular Metal Tibial Cone

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Augments (K102896). The subject OsseoTi augments are constructed from a previously cleared material/manufacturing process.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

OsseoTi material characterization tests and construct testing used in support of the substantial equivalence included the following:

Construct testing / justifications:

- Static Axial (Pull Off) Force
- Torque Resistance
- Fatigue
- Fretting
- MRI Compatibility Justification

OsseoTi characterization:

- Interconnecting Porosity
- Micrographs
- Porosity and Pore Size
- Roughness
- Abrasion Resistance
- Mechanical Strength
- Chemical Composition
- Shear Fatigue
- Static Shear
- Static Tensile

Animal Data

All testing met or exceeded the established acceptance criteria.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: None provided as a basis for substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The culmination of the results of the mechanical construct testing, OsseoTi characterization and animal data indicated the devices performed within the intended use, did not raise any new safety and efficacy issues, and are substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 30, 2014

Biomet, Incorporated
Mr. Jason Heckaman
Regulatory Affairs Project Manager
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0857

Re: K140883
Trade/Device Name: Vanguard® 360 OsseoTi™ Tibial Sleeve Augments
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: July 1, 2014
Received: July 2, 2014

Dear Mr. Heckaman:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

Indications for Use

510(k) Number (if known): K140883

Device Name: – Vanguard® 360 Osseo™ Ti Tibial Sleeve Augments

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

The Regenerex femoral augments are indicated for use with the Vanguard Total Knee System.

The Regenerex tibial augments are indicated for use with standard and offset Biomet® Tibial Trays.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok) femoral components, tibial tray components and all polyethylene patellar components are indicated for cemented application only. Regenerex and OsseoTi components are intended only for uncemented biologic fixation application.

The Vanguard DA 360 components are not intended for use with the Vanguard PS Open Box Porous Femoral components. **The Vanguard DA 360 components are not approved for sale in the United States.**

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(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)

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Division of Orthopedic Devices