Section 5
510(k) Summary

MAR 1 1 2014

NAME OF SPONSOR:	Ortho Development Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) CONTACT:	Mike Ensign Director of Regulatory Affairs and Quality Assurance Telephone: (801) 553-9991 Facsimile: (801) 553-9993 Email: mensign@odev.com
DATE PREPARED:	October 28, 2013
PROPRIETARY NAME:	Ovation Tribute Hip Stem Ovation Narrow Hip Stem
COMMON NAME:	Hip Stem Prosthesis
CLASSIFICATION:	Class II device 21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
DEVICE PRODUCT CODE:	LPH
PREDICATE DEVICES:	Ovation® Hip Stem, *Ortho Development* (K062775) Ovation 10/12 Hip Stem, *Ortho Development* (K131022) Taperloc® Complete Microplasty System, *Biomet* (K110400) Smith & Nephew SMF Hip Stem, *Smith & Nephew* (K103256)

5.1. Device Description

The Ovation Tribute and Ovation Narrow Hip Stems are one-piece, tapered prostheses, designed for single, uncemented use. Device fixation is achieved via press-fit in the medullary canal, which maximizes contact between the stem and bone. The stems are manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F136. Proximally, the stems are coated with titanium plasma spray per ASTM F1580. The stems have a neck with a 12/14 trunnion taper for modular attachment to femoral heads. To accommodate varying patient anatomy, the stems are available in a variety of sizes: lengths (74-142mm), horizontal offsets (34-49mm), vertical offsets (29-36mm), resection angle of 130°, and neck angle of 132°.

5.2. Intended Use

The Ovation Tribute and Ovation Narrow Hip Stems are intended for use in a total hip replacement surgery. Total hip arthroplasty is intended to provide increased patient mobility and to decrease pain by replacing the damaged hip joint in patients having sufficiently sound bone to support the implants.

5.3. Indications for Use

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

5.4. Summary of Technological Characteristics

The Ovation Tribute and Ovation Narrow Hip Stems represent an update to the existing predicate device Ovation® Hip Stem (K062775). The Ovation Tribute and Ovation Narrow Hip Stems combine the design features of the Ovation® Hip Stem (K062775) with a narrowed distal body to accommodate varying patient anatomy. Additionally, the Ovation Tribute stem features a reduced overall length in order to provide a microplasty option. The Ovation Tribute and Ovation Narrow Hip Stems have the same technological characteristics as the predicate devices. These include:

- Intended use (as described above)
- Basic design
- Material
- Sizes

Therefore, the fundamental scientific technology of Ovation Tribute and Ovation Narrow Hip Stems is the same as previously cleared devices.

5.5. Basis of Substantial Equivalence

The Ovation Tribute and Ovation Narrow Hip Stems are substantially equivalent to the previously cleared predicate devices based on similarities in intended use, overall design, materials, manufacturing methods, packaging, mechanical performance, and sterilization.

5.6. Non-Clinical Test Summary

Non-clinical performance testing has been conducted in proximal fatigue in accordance with ISO 7206-6:1992 and distal fatigue in accordance with ISO 7206-4:2010. Range of motion analysis was performed per ISO 21535:2007(E). The plasma spray coating underwent testing for mechanical properties and microstructure analysis.

5.7. Clinical Test Summary

No clinical studies were performed.

5.8. Conclusions

Based on the similarities to the predicate devices, and a review of the testing, the devices are substantially equivalent to femoral stem components that were cleared under K062775, K131022, K110400, and K103256.

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

March 11, 2014

Ortho Development Corporation
Mr. Mike Ensign
Director of Quality Assurance/Regulatory Affairs
12187 South Business Park Drive
Draper, Utah 84020

Re: K133386
Trade/Device Name: Ovation Tribute Hip Stem; Ovation Narrow Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: January 28, 2014
Received: January 29, 2014

Dear Mr. Ensign:

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 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. 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,

Lori A. Wiggins

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133386

Device Name
Ovation Tribute Hip Stem; Ovation Narrow Hip Stem

Indications for Use *(Describe)*

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth D Frank -S

Division of Orthopedic Devices

FORM FDA 3881 (9/13)

[redacted]

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