JUL 30 2014

Section 5
510(k) Summary

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:	July 18, 2014
Proprietary Name:	Alpine Hip Stem
Common Name:	Hip Stem Prosthesis
Classification:	21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II device
Device Product Code:	LPH, LZO, KWY, KWL, MBL
Predicate Devices:	Ovation™ Hip Stem (K062775) *Ortho Development* Global Taper Tapered Hip System (K963509) *Smith & Nephew* Novation 12/14 Press-Fit Femoral Stem (K042842) *Exactech*

Device Description

The Alpine Hip Stem is a single-piece, conical tapered femoral hip prostheses, designed for single, cementless use. The stem has a neck with a 12/14 trunnion for modular attachment to femoral heads.

The Alpine Hip Stem is manufactured from titanium alloy (per ASTM F136, Ti-6Al-4V ELI) and device fixation is achieved via press-fit in the medullary canal, which maximizes contact between the stem and bone. The proximal portion is plasma sprayed with titanium alloy (per ASTM F1580).

Intended Use

The Alpine Hip Stem is intended for use in total hip replacement surgery or hemi-arthroplasty. Hip arthroplasty is intended to provide increased patient mobility and decrease pain by replacing the damaged hip joint in patients having sufficiently sound bone to support the implants.

Indications for Use

This device is intended for use in total hip arthroplasty or hemi-arthroplasty. The device is intended for uncemented, press-fit use only in cases of:

1. Notably impaired hip joints 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

Summary of Technological Characteristics

The Alpine Hip Stem has the same technological characteristics as the predicate devices. The subject device stem is a single-piece, conical tapered uncemented hip stem. The stem has proximal stem geometry to aid in the fill and locking in the medullary canal. The conical tapered distal stem has a circular cross-section for fit in the medullary canal. Compared to the predicate devices, the Alpine Hip Stem has the same intended use, basic design, and materials.

Basis of Substantial Equivalence

The Alpine Hip Stem is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, overall design, materials, manufacturing methods, packaging, mechanical performance and sterilization.

Test Summary

Non-clinical performance testing has been conducted in proximal fatigue in accordance with ISO 7206-6:2013 and distal fatigue in accordance with ISO 7206-4:2010. Range of motion analysis was performed per ISO 21535:2007. The plasma spray coating underwent testing for mechanical properties and microstructure analysis. No clinical studies were performed.

Conclusions

Based on the similarities to the predicate devices, and a review of the testing, the Alpine Hip Stem is substantially equivalent to the predicate devices that were cleared under K062775 and K963509.

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

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

Re: K141001
Trade/Device Name: Alpine 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, LZO, MBL, KWY, KWL
Dated: July 10, 2014
Received: July 11, 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 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" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141001

Device Name
Alpine Hip Stem

Indications for Use *(Describe)*
This device is intended for use in total hip arthroplasty or hemi-arthroplasty. The device is intended for uncemented, press-fit use only in cases of:

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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