



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

Ortho Development Corporation
Drew Weaver
Director of Quality Assurance and Regulatory Affairs
12187 South Business Park Drive
Draper, Utah 84020

February 18, 2016

Re: K153216

Trade/Device Name: Alpine[®] Cemented Hip System

Regulation Number: 21 CFR 888.3350

Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: Class II

Product Code: JDI, KWL, KWY, LPH, LZO, MBL

Dated: November 3, 2015

Received: November 5, 2015

Dear Drew Weaver:

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 Parts 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,

Mark N. Melkerson -S

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

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

Indications for Use

510(k) Number (if known)

Device Name

Alpine® Cemented Hip System

Indications for Use (Describe)

This device is intended for use in total and hemi hip arthroplasty. The device is intended for single, cemented 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 the 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

12187 So. Business Park Drive
 Draper, Utah 84020
 801-553-9991/fax 553-9993

orthodevelopment.com



Section 5 510(k) Summary

Name of Sponsor: Ortho Development Corporation
 12187 South Business Park Drive
 Draper, Utah 84020

510(k) Contact: Drew Weaver
 Director of Quality Assurance and Regulatory Affairs
 Telephone: (801) 553-9991
 Facsimile: (801) 553-9993
 Email: DWeaver@orthodevelopment.com

Date Prepared: February 17, 2016

Trade Name: Alpine® Cemented Hip System

Common Name: Total and Hemi Hip Replacement Prosthesis

Device Product Code/Classification: JDI- 21 CFR 888.3350, Hip joint metal/polymer semi-constrained cemented prosthesis

Subsequent Device Product Codes/Classifications: KWL- 21 CFR 888.3360, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

KWY- 21 CFR 888.3390, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis

LPH- 21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

LZO- 21 CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

MBL- 21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Device Class: Class II

Predicate Devices: Encompass™ Cemented Hip System, K050637, Ortho Development Corporation
 Synergy Cemented Hip Stems, K990369, Smith & Nephew

Device Description

Alpine® Cemented Hip System is comprised of a single piece, conical tapered, collared, femoral hip stem and centralizer designed for single, cemented use. Alpine® Cemented Hip Stem is manufactured from cobalt-chrome alloy (per ASTM F799-11) and Alpine® Centralizer is manufactured from poly(methyl methacrylate), PMMA. See MAF-300, PolyOne Corporation. Device fixation is achieved by cement mantle in the medullary canal.

Alpine® Cemented Hip Stem has a neck with a 12/14 trunnion for modular attachment to femoral heads and is offered in a variety of sizes to accommodate various patient anatomies. Sizes include the following ranges: lengths (114-132mm), horizontal offsets (35-48mm), and vertical offsets (26-30mm), with a resection angle of 40° and a neck angle of 130°.

Alpine® Centralizer is offered in sizes 8mm to 18mm in diameter to accommodate various combinations of stem/centralizer diameters depending on surgeon preference.

Intended Use

Alpine® Cemented Hip System is intended for use in total and hemi hip replacement surgery.

Indications for Use

This device is intended for use in total and hemi hip arthroplasty. The device is intended for single, cemented 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 the 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

Alpine® Cemented Hip System has the same technological characteristics as the predicate devices. Subject device stem is single piece, conical tapered, and collared. The proximal body has a recess in the anterior and posterior walls to aid in proximal cement fixation. The distal body has flattened geometries in the anterior and posterior walls to aid in distal cement fixation. The highly polished neck has an oval cross section for increased range of motion.

Subject device centralizer uses a tapered pin for fixation with the stem. It has 3 fins that aid in centering the stem within the medullary canal.

Basis of Substantial Equivalence

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

Non-Clinical Test Summary

Non-clinical performance testing has been conducted in proximal fatigue in accordance with ISO 7206-6:2013(E) and distal fatigue in accordance with ISO 7206-4:2010(E). Range of motion analysis was performed per ISO 21535:2007(E).

Clinical Test Summary

No clinical studies were performed.

Conclusions

Based on the similarities to the predicate devices, and a review of testing, Alpine® Cemented Hip System is substantially equivalent to predicate devices cleared in K050637 and K990369.