K051023

NOV 15 2005

510(k) Summary

Topez Orthopedics, Inc.
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303-530-0637

Lewis Ward
Consultant

Prepared 10-20-05

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Topez Total Ankle Replacement

Indications for Use:

Total ankle arthroplasty is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic or degenerative arthritis.

The ankle prosthesis is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cemented use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (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)

Device: Ankle Prosthesis

Common Name: Ankle prothesis

SE Predicate: DePuy Inc.
Agility Ankle
K020541
888.3110

Device Description:

Summary: The Topez prosthesis is a total ankle joint replacement medical device. It is a semi-constrained, cemented prosthesis. It is intended to be an equivalent product to the DePuy's FDA-cleared "Agility" model, with the same indications for use.

Components: Listed below are the components comprising the Topez ankle prosthesis assembly.

1. Tibial-side replacement (tibial platform): This is a titanium (Ti-6Al-4V, ELI) structural component that holds and secures the Ultra High Molecular Weight Polyethylene (UHMWPE: GUR 1020, ASTM F648) component and interfaces with the Tibial Stem Assembly (both described below)
2. UHMWPE: This is a concave component that replaces the physiological distal end of the tibia. It is one of the two major bearing surfaces in the ankle joint replacement system. The UHMWPE snap-locks within a tibial platform using a design similar to knee replacement systems.
3. Tibial Stem Assembly: This is a titanium (Ti-6Al-4V, ELI) anchor-interface by which the tibial platform component is secured to the tibia. It consists of 4 titanium cylinders that are screwed together to form a long stem up within the center of the tibia. There are four components to be inserted through a small anterior incision in the ankle, screwed together and then pushed up into the center of the drilled tibia. The 4-stem assembly is finally secured to the tibial platform with a Morse taper lock system that is common with joint implants.
4. Talar-side replacement (talar platform): This is a convex Cobalt-Chrome (Co-Cr-Mo, ASTM F1537) bearing surface on the talar side of the ankle joint. In concert with the UHMWPE, it forms the sliding-rotating joint interface of the ankle joint. It serves the second function of providing the interface-anchor to the talus.
5. Talar Stem: This is a titanium (Ti-6Al-4V, ELI) anchor-interface by which the talar platform component is secured to the talus. The Talar Stem is attached to the Talar platform with a Morse taper lock system that is common with joint implants.

The Topez prosthesis is comprised entirely of materials now used for other implant products. The Topez ankle is intended to be used with a tibial anchor that is larger than those that are typically seen with ankle prostheses. The Topez ankle utilizes a Foot-Leg holder assembly with jigs and fixtures intended to assist the surgeon with an accurate and simple prosthesis installation tool-kit.

Comparative Information

Feature	DePuy, Inc. – Agility	Topez Orthopedics, Inc.
Indications for Use	Total ankle arthroplasty is intended to give a patient limited mobility to reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic or degenerative arthritis. The ankle prosthesis is additionally indicated for patients with a failed previous ankle surgery. Caution: The ankle prosthesis is intended for cemented use only.	Total ankle arthroplasty is intended to give a patient limited mobility to reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic or degenerative arthritis. The ankle prosthesis is additionally indicated for patients with a failed previous ankle surgery. Caution: The ankle prosthesis is intended for cemented use only.
Classification 510(k) Number Description	888.3110, Class II, Orthopedic 87 HSN K020541 Modular Semi-Constrained Total Ankle Replacement - limited patient mobility - replaces flexion and extension of ankle joint Alternative to ankle fusion Imitates structure and movement of the natural ankle joint Normal alignment during stance phase	888.3110, Class II, Orthopedic 87 HSN K051023 Modular Semi-Constrained Total Ankle Replacement - limited patient mobility - replaces flexion and extension of ankle joint Alternative to ankle fusion Imitates structure and movement of the natural ankle joint. Normal alignment during stance phase

	DePuy, Inc. – Agility	Topez Orthopedics, Inc.
	Comfortable movement during walking cycle – 60 degrees of rotation	Comfortable movement during walking cycle – 50 degrees of rotation
	Broad base tibial component Proper sizing: Multiple sizes – 6 sizes Materials: Tibia – Ultra High Molecular Weight Polyethylene Base Plate Tray – titanium Talar – cobalt chromium alloy Broad base tibial components Tapered talar component Accessory: Cutting jig Class I Tool Kit Class I Gas Plasma Sterilization DePuy Training Prerequisite	Broad base tibial component Proper sizing: Multiple sizes – 6 sizes Materials: Tibia – Ultra High Molecular Weight Polyethylene Base Plate Tray – titanium Talar – cobalt chromium alloy Broad base tibial components Tapered talar component Accessory: Cutting jig Class I Tool Kit Class I Gamma Sterilization Topez Training Prerequisite
Coated	Porous coated distal surface and fin talar components	Plasma spray coated distal talar surface, proximal tibial surface, tibial stem & talar stem
Contact Area Talus & UHMWPE Size 1 Size 2 Size 3 Size 4 Size 5 Size 6	 0.209 sq. in. 0.271 0.296 0.41 0.558 0.767	 0.569 sq. in. 0.718 0.884 1.068 1.268 1.486

	DePuy, Inc. – Agility	Topez Orthopedics, Inc.
Contact Stresses at 5 BW Talus & UHMWPE (Calculated by F/A or 5BW/Contact Area)		
Size 1	3899 psi	1432 psi
Size 2	3007 psi	1135 psi
Size 3	2753 psi	922 psi
Size 4	1988 psi	763 psi
Size 5	1461 psi	643 psi
Size 6	1063 psi	548 psi

Similarities and Differences

Indications for Use are the same for total ankle replacement.

Both are intended for cemented use only.

Six sizes are available for both devices.

The design concepts are equivalent.

The DePuy Tibial Tray uses a "keel" design approximately 10 mm in height. The Topez design is 10 mm.

The Talar Stem on the DePuy is also a "keel" design approximately 10 mm. Topez's design is 10 mm.

The DePuy tibial tray has integral sidewalls for Medial-Lateral constraint of the talus. Topez's design relies on the natural physiological constraint provided by the fibula, medial malleolus and concavity of the talar dome/UHMWPE interface. (See: "Test 2: Determining the Constraint Characteristics of a Total Ankle Replacement"

Both devices have Accessory Cutting Jigs and Tool Kits used in the surgical process.

The DePuy prosthesis is designed to $\pm$30 degrees rotation. Topez's rotation is $\pm$25 degrees, equal to the human anatomical range of motion for a walking gait.

Sterilization is accomplished by Gamma Radiation, different from DePuy but comparable.

Surgical training is required by both manufacturers as a prerequisite to implant the individual devices.

Porous coatings are used with both manufacturers' products. The plasma spray used by Topez accomplishes the same intended use as the porous coat used in the DePuy device. Use of the plasma spray by Topez does not bring up new issues of safety.

Contact area of the talus and UHMWPE is increased in the Topez prosthesis for reduced material stresses.

NON-CLINICAL DATA

1. Risk Management following ISO 14971 demonstrates acceptable and mitigated potential hazards. Hazard Analysis is supported with Finite Element Analysis and Failure Modes Effects and Analysis.

2. Structural materials used meet ASTM standards:
    a. Cobalt-Chromium-Molybdenum, ASTM F1537
    b. Titanium, Ti-6A1-4V ELI, ASTM F136
    c. UHMWPE, GUR1020, ASTM F648

3. Performance Testing
    a. Test 1, Determining the Contact Surface Area and Stresses of a Total Ankle Replacement Articulating Surfaces – PASSES
    b. Test 2, Determining the Constraint Characteristics of a Total Ankle Replacement – PASSES
    c. Test 3, Determining the Disassembly Strength of the Tibial Tray and UHMPWE Insert of a Total Ankle Replacement With and Without Joint Reaction Force – PASSES
    d. Test 4, Test Protocol for Determining the Fatigue Strength of Tibial Stems of a Total Ankle Replacement - PASSES
    e. Test 5, Test Protocol for Disassembly Strength of a Calcaneal Stem – PASSES
    f. Test 6, Determining the Assembly/Disassembly Strength of the Tibial Stem of a Total Ankle Replacement - PASSES

4. There are no new questions concerning safety and effectiveness.

Conclusion: The ankle prosthesis is designed, labeled, and verified for performance and safety. The device is substantially equivalent to legally marketed predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 15 2005

Topez Orthopedics, Inc.
c/o Lewis Ward, Consultant
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K051023
Trade/Device Name: Topez Total Ankle Replacement
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSN
Dated: October 20, 2005
Received: October 24, 2005

Dear Mr. Ward:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051023