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K063054

3 510(k) Summary of Safety and Effectiveness

Manufacturer/Sponsor	Arthrex, Inc.1370 Creekside Boulevard Naples, Florida 34108-1945
510(k) Contact	Nancy Hoft Regulatory Affairs Associate Telephone: 239/643.5553, ext. 1113 Fax: 239/598.5539 Email: nhoft@arthrex.com
Trade Name	Arthrex AnaToemic™ Phalangeal Prosthesis
Common Name	Prosthesis, Toe, Hemi-, Phalangeal
Product Code	**KWD**
Predicate Devices	**K031859**, CAP™ Great Toe Resurfacing Hemi-Arthroplasty **K041595**, BioPro Hemi MP Joint
Device Description and Intended Use	The Arthrex AnaToemic™ Phalangeal Prosthesis is a one-piece implant system that replaces only half of the affected joint of the metatarso-phalangeal joint of the big toe. It is anatomically designed to provide an optimal fit to the distal articular surface of the affected joint. The implant has two design elements: 1) a polished, concave oval disk; and, 2) a rough stem with a barbed trapezoid shape with a lozenge cross section. On the stem as well as on the distal portion of the disc the surface is rough. The implant material is cobalt chromium alloy (ASTM F1537). The Arthrex AnaToemic™ Phalangeal Prosthesis is a press-fit implant that is intended to be used in patients with hallux limitus, hallux rigidus, hallux valgus, arthritic degradation of the metatarso-phalangeal joint, degenerative arthritis, rheumatoid arthritis, and bunion deformity associated with arthritis of the metatarsal-phalangeal joint.
Substantial Equivalence Summary	Arthrex has determined that the Arthrex AnaToemic™ Phalangeal Prosthesis is substantially equivalent to the predicate device where basic features and intended uses are the same. Any design differences between the Arthrex AnaToemic™ Phalangeal Prosthesis and the predicate device are considered minor and do not raise any questions concerning safety and effectiveness. Any differences have been found to have no apparent effect on the performance, function, or intended use of the device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Arthrex, Inc.
% Ms. Nancy Hoft
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108

Re: K063058
Trade/Device Name: Arthrex AnaToemic™ Phalangeal Prosthesis
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: October 2, 2006
Received: October 6, 2006

Dear Ms. Hoft:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

K063058

2 Indications for Use Form

Indications for Use

510(k) Number: _____

Device Name: Arthrex AnaToemic™ Phalangeal Prosthesis

The Arthrex AnaToemic™ Phalangeal Prosthesis is a press-fit implant that is intended to be used in patients with hallux limitus, hallux rigidus, hallux valgus, arthritic degradation of the metatarso-phalangeal joint, degenerative arthritis, rheumatoid arthritis, and bunion deformity associated with arthritis of the metatarsal-phalangeal joint.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 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 Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063058