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Section 5 — 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson Director, Quality Systems
Date of Preparation:	October 18, 2006
Trade Name:	Contoured Articular Prosthetic (CAP) ™ 7.0mm MTP Resurfacing Hemi-arthroplasty
Common Name:	7.0mm MTP Resurfacing Prosthesis
Device:	Prosthesis, Toe, Hemi-, Phalangeal
Classification Regulation:	Regulation Number 888.3730
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	KWD

JAN 12 2007

Device Intended Use

Hemi-arthroplasty implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

Device Description

The 7.0mm MTP Taper Post is a reduced length and diameter version of the sponsor's previously cleared and commercially marketed 8.0mm Taper Post, but is otherwise identical.

Substantial Equivalency:

The intended use, materials, design features and application of the Proposed Device are substantially equivalent to the sponsor's previously cleared and commercially marketed device (K031859 Toe joint phalangeal (hemi-toe) polymer prosthesis, Arthrosurface, Inc.).

The fundamental scientific technology of the proposed device has not changed relative to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrosurface, Inc.
% Ms. Dawn Wilson
Director, Quality Systems
28 Forge Parkway
Franklin, Massachusetts 02038

JAN 12 2007

Re: K063370
Trade/Device Name: Contoured Articular Prosthetic CAP™ 7.0mm
MTP Resurfacing Hemi-arthroplasty
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: November 2, 2006
Received: November 13, 2006

Dear Ms. Wilson:

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,

Barbara Fuchs
for

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

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K063370

Device Name: Contoured Articular Prosthetic (CAP) ™
7.0mm MTP Resurfacing Hemi-arthroplasty

Indications for Use:

Hemi-arthroplasty implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K063370