K071413

Section 5 – 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
	NOV 0 9 2007
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	May 10, 2007
Trade Name:	HemiCAP™ Patello-Femoral Resurfacing Prosthesis
Common Name:	Knee Joint Patello-Femoral Resurfacing Prosthesis
Device:	Prosthesis, Knee, Patello/Femoral, Semi-Constrained, Cemented, Metal/Polymer
Classification Regulation:	Regulation Number 888.3540
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	KRR

Device Intended Use

The HemiCAP™ Patello-Femoral Resurfacing Prosthesis is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

Device Description

The FFL0-XXXX Patello-Femoral, Femoral Component, Large is a line extension to the Sponsor's previously cleared and commercially marketed HemiCAP™ Patello-Femoral Resurfacing Prosthesis.

This configuration is designed to allow for increased surface area of the femoral trochlear groove to provide greater coverage laterally as well as for increased flexion and extension angles.

The proposed component is designed to mate with FFS1-XXXX Patello-Femoral Fixation Stud via taper interlock as well as the Sponsor's previously cleared and commercially marketed all-polyethylene patella component.

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 (K060127 HemiCAP™ Patello-Femoral Resurfacing 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

NOV 0 9 2007

Arthrosurface, Inc.
% Ms. Dawn Wilson
VP, Quality & Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K071413
Trade/Device Name: HemiCAP™ Patello-Femoral Resurfacing Prosthesis
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: October 3, 2007
Received: October 12, 2007

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.

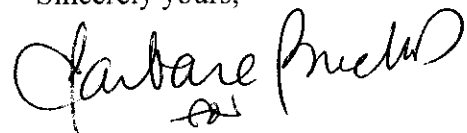
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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): K071413

Device Name: HemiCAP™ Patello-Femoral Resurfacing Prosthesis

Indications for Use:

The HemiCAP™ Patello-Femoral Resurfacing Prosthesis is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

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

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

510(k) Number K071413