K073068 (pg 1/1)

Summary of Safety and Effectiveness

Submitter: Michael Kvitnitsky
Accelerated Innovation, LLC
1033 US Highway 46, Suite A204
Clifton, NJ 07103

JAN 10 2008

Date Prepared: October 10, 2007

Device: Accin™ Hip System

Classification: 87 LPH - Hip joint metal/polymer/metal semi-constrained uncemented prosthesis, 21 CFR 888.3358, Class II and 87 HWC and screw, fixation, bone, 21 CFR 888.3040, Class II

Predicate Device: Provident Hip System – K935484, K946371, K960180, K991622 K001745, and K002796 and Stelkast Bone Screws – K934162

Device Description: The Accin™ Hip System consists of plasma spray coated titanium alloy femoral component, a cobalt chrome femoral head, a plasma spray coated titanium alloy acetabular shell, bone screws and a polyethylene acetabular insert.

Intended Use: The Accin™ Hip System components are for use in total hip arthroplasty as a result of:

- Hip arthritis caused by rheumatoid disease, non-inflammatory degenerative joint disease, osteoarthritis, and arthritis resulting from biologic or mechanical trauma to the hip
- Correction of functional deformity
- Avascular Necrosis
- Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur
- Difficult clinical management problems involving persistent pain and physical impairment where conventional arthodesis is not likely to achieve satisfactory results

These components are single use only and are intended for implantation without bone cement.

Comparison to Predicates:
The Accin™ Hip system consists of cobalt chrome femoral head, titanium alloy femoral stem, acetabular components plasma spray coated with CP Titanium, bone screws and an acetabular polyethylene insert. The device is equivalent to the Stelkast Provident Hip System, which also has the same components manufactured from the same materials.

Accin™ has determined that any differences in the proposed device will not impact the safety or effectiveness of the hip system for its intended use. Testing has shown that the proposed device meets the requirements of the current FDA Guidance documents on total hip arthroplasty product and the proposed device is equivalent to the predicate device.

Synopsis of Test Methods and Results:
Tests were performed on the Hip System. The tests performed can be found in the guidance documents entitled "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements;" "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis;" and "Guidance for Industry and FDA Staff - Non-clinical Information for Femoral Stem Prostheses."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2008

Accelerated Innovation, LLC
% Mr. Michael Kvitnitsky
1033 US Highway 46
Suite A204
Clifton, NJ 07103

Re: K073068
Trade/Device Name: Accin™ Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, HWC
Dated: December 21, 2007
Received: December 27, 2007

Dear Mr. Kvitnitsky:

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

 K073068 (pg 1/1)

Indications for Use Form

510(k) Number (if known):_____

Device Name: Accin™ Hip System

Indications for Use:

Indications for Use:
The Accin™ Hip System components are for use in total hip arthroplasty as a result of:

- Hip arthritis caused by rheumatoid disease, non-inflammatory degenerative joint disease, osteoarthritis and arthritis resulting from biologic or mechanical trauma to the hip
- Correction of functional deformity
- Avascular necrosis
- Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur
- Difficult clinical management problems involving persistent pain and physical impairment where conventional arthodesis is not likely to achieve satisfactory results.

These components are single use only and are intended for implantation without bone cement.

Prescription Use ___X____ (Per 21 CFR 801.109) OR Over-The-Counter Use_____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K073068