JUN - 2 2008

Summary of Safety and Effectiveness

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

Date Prepared: February 3, 2008

Device: Accin™ Unipolar Head

Classification: 87 JDI - Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented, 21 CFR 888.3350, Class II

Predicate Device: Stelkast Endo Prosthesis Femoral Head – K952461

Device Description: The Accin™ Unipolar Head System consists of a cobalt chrome modular endo prosthesis femoral head.

Intended Use: The Accin™ Unipolar Head is intended to be implanted for use in the reconstruction of the femoral portion of severely disabled and / or very painful hip joints resulting from:

- Osteoarthritis;
- Rheumatoid Arthritis;
- Traumatic Arthritis;
- Avascular Necrosis

The device is only for use where sufficient sound bone to seat the prosthesis is present and for use with the Accin Hip Stems.

Comparison to Predicates:
The Accin™ Unipolar Head consists of cobalt chrome femoral head. The device is equivalent to the Stelkast Unipolar Head System, which also has the same component manufactured from the same material.

Accin™ has determined that any differences in the proposed device will not impact the safety or effectiveness of the unipolar system for its intended use. Testing has shown that the proposed device the proposed device is equivalent to the predicate device.

JUN - 2 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Accin Corporation
% Mr. Michael Kvitnitsky
Chief Operating Officer
1033 U.S. Highway 46 East
Suite A204
Clifton, New Jersey 07013

JUN - 2 2008

Re: K080539
Trade/Device Name: Accin™ Unipolar Head System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulation Class: Class II
Product Code: JDI
Dated: May 9, 2008
Received: May 12, 2008

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 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

Indications for Use Form

510(k) Number (if known): K080539

Device Name: Accin™ Unipolar Head (Modular Endo Head)

Indications for Use:

The Accin™ Unipolar Head is intended to be implanted for use in the reconstruction of the femoral portion of severely disabled and / or very painful hip joints resulting from:

- Osteoarthritis;
- Rheumatoid Arthritis;
- Traumatic Arthritis;
- Avascular Necrosis;

The device is only for use where sufficient sound bone to seat the prosthesis is present and for use with the Accin Hip Stems.

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)

Neil R. P. Ogden for AKS

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

510(k) Number K080539