

K080647

Summary of Safety and Effectiveness

- Submitter:** Michael Kvitnitsky
Accelerated Innovation, LLC
1033 US Highway 46, Suite A204
Clifton, NJ 07103
- Date Prepared:** February 28, 2008
- Device:** Accin™ Bipolar Head
- Classification:** 87 KWY - Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented - 21 CFR 888.3390, Class II
- Predicate Device:** Stelkast Bipolar Head System – K981451
- Device Description:** The Accin™ Bipolar Head System consists of a cobalt chrome femoral head with a preassembled polyethylene insert and a snap ring that locks the head into the insert.
- Intended Use:** The Accin™ Bipolar Head components are intended to be implanted to replace a portion of the hip for:
- Fractures of the proximal femur;
 - Non-unions of proximal femoral neck fractures;
 - Aseptic necrosis of the femoral head;
 - Osteo-rheumatoid and post traumatic arthritis of the hip with minimal distortion of the acetabulum; and
 - Salvage of failed total hip arthroplasty.

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

Comparison to Predicates:

The Accin™ Bipolar Head consists of cobalt chrome femoral head with a preassembled polyethylene insert and polyethylene snap ring. The device is equivalent to the Stelkast Bipolar Head 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 bipolar system for its intended use. Testing has shown that the proposed device is equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Accelerated Innovation, LLC
% Mr. Michael Kvitnitsky
Chief Operating Officer
1033 US Highway 46 East, Suite A204
Clifton, NJ 07013

Re: K080647
Trade/Device Name: ACCIN™ Bipolar Head System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi hip) metal/polymer
cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: June 6, 2008
Received: June 10, 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.

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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

Indications for Use Form

510(k) Number (if known): _____

Device Name: Accin™ Bipolar Head

Indications for Use:

The Accin™ Bipolar Head components are intended to be implanted to replace a portion of the hip for:

- Fractures of the proximal femur;
- Non-unions of proximal femoral neck fractures;
- Aseptic necrosis of the femoral head;
- Osteo-rheumatoid and post traumatic arthritis of the hip with minimal distortion of the acetabulum; and
- Salvage of failed total hip arthroplasty.

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

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)

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**Division of General, Restorative,
and Neurological Devices**

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