K060670

Summary of Safety and Effectiveness

Submitter: Michael Kvitnitsky
ACCIN Corporation
1033 US Highway 46, Suite A204
Clifton, NJ 07103

JUN - 2 2006

Date Prepared: February 18, 2006

Device: ACCIN UNI-Knee System

Classification: 87 HSX - Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer, 21 CFR 888.3520, Class II

Predicate Device: EIUS Unicompartmental Knee System – K033769 and K992287
Stelkast Unicondylar Knee System – K0032824
Zimmer Unicompartmental Knee System – K033363

Device Description: The ACCIN UNI-Knee System consists of Cobalt Chrome femoral component and tibial tray and a polyethylene tibial insert.

Intended Use: The ACCIN UNI-Knee System components are for use in Unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis;
- Correction of functional deformities;
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure;
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

These components are single use only and are intended for implantation with bone cement.

Comparison to Predicates:
The ACCIN UNI-Knee system consists of cobalt chrome femoral and tibial components and a polyethylene insert. The device is similar to the Stelkast Unicondylar Knee System, the EUIS Unicompartmental Knee system and the Zimmer High Flex Unicompartmental Knee System. All three devices are for use in unicompartmental knee replacement. The Zimmer product and the proposed ACCIN device have a metal tibial tray and a UHMWPE tibial insert; whereas the EUIS system and the Stelkast system have an all-polyethylene tibia.

ACCIN Corporation has determined that the minor differences in the proposed device will not impact the safety or effectiveness of the unicompartmental knee system for its intended use. Testing has shown that the proposed device is equivalent to the predicate device.

Synopsis of Test Methods and Results:
Tests were performed on the ACCIN UNI-Knee System as compared to the Stelkast Unicondylar Knee System. The tests performed can be found in the guidance document entitled "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA." The results provided in the testing section of this submission demonstrate that the proposed ACCIN UNI-Knee System is equivalent to the predicate device Stelkast Unicondylar Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

ACCIN Corporation
% Mr. Michael Kvitnitsky
1033 US Highway 46 East
Suite A204
Clifton, New Jersey 07013

Re: K060670
Trade/Device Name: ACCIN UNI-Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: March 06, 2006
Received: March 14, 2006

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

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,

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

Enclosure

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

Indications for Use Form

510(k) Number (if known):_____

Device Name: ACCIN UNI-Knee System

Indications for Use:

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The ACCIN UNI-Knee System components are for use in Unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis;
- Correction of functional deformities;
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure;
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

These components are single use only and are intended for implantation with 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 K060670