K073530

## Summary of Safety and Effectiveness

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

**Date Prepared:** December 10, 2007

JAN 31 2008

**Device:** Accin™ Cervical Plate System

**Classification:** 87KWQ – Appliance, Fixation, Spinal Intervertebral Body, 21CFR 880.3060, Class II

**Predicate Device:** Vertebron SCP and SSP Cervical Plate Systems – K040003, K043181, K051815 and K062110

**Device Description:** The Accin™ Cervical Plate System consists of titanium cervical plates and both self-tapping and self-drilling screw components. The surgeon uses the components to make a construct that is placed anteriorly for spinal fixation. The construct is used for temporary fixation which allows for fusion of the cervical spine

**Intended Use:** The Accin™ Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disk disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); trauma (including fracture); tumor; deformity (defined as kyphosis, lordosis or scoliosis); pseudoarthrosis; and/or failed previous fusions. The Accin™ Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7.

**Comparison to Predicates:**
The Accin™ Cervical Plate System consists of plates and screws manufactured from the same titanium alloy as the Vertebron, Inc. SPC and SSP Cervical Plate Systems. Therefore, the devices are equivalent to the Vertebron, Inc. SPC and SSP Cervical Plate Systems.

Accin™ has determined that any differences in the proposed device will not impact the safety or effectiveness of the cervical plate system for its intended use. Testing has shown that the proposed device meets the requirements of the current FDA Guidance document entitled "Spinal System 510(k)s" dated May 3, 2004, and that the proposed device is equivalent to the predicate device.

**Synopsis of Test Methods and Results:**
Tests were performed on the cervical plate system. The testing was performed in accordance with ASTM F1717, Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model. The proposed device was equivalent to the predicate device for all testing performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Accelerated Innovations, LLC
% Mr. Michael Kvitnitsky
Chief Operating Officer
1033 US Highway 46, Suite A204
Clifton, NJ 07103

Re: K073530
Trade/Device Name: Accin™ Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 12, 2007
Received: December 19, 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

## Indications for Use Form

510(k) Number (if known):_____

Device Name: Accin™ Cervical Plate System

Indications for Use:

The Accin™ Cervical Plate System components are intended for anterior interbody fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with:

- Degenerative disk disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Trauma (including fractures)
- Tumor
- Deformity (defined as kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusions.

The Accin Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7.

Prescription Use ___X___ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (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 K673530