K081597

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5. 510(k) Summary or 510(k) Statement

SUBMITTER:

VERTEBRON Inc.
80 Hathaway Drive
Stratford, CT 06615
(203) 380-9340

CONTACT PERSON:

Luis Nesprido
Senior Manager, Regulatory and Quality Affairs

DATE PREPARED: May 23, 2008

CLASSIFICATION NAME:

21 CFR §888.3050 Spinal Interlaminal Fixation Orthosis
21 CFR §888.3060 Spinal Intervertebral Fixation Orthosis
21 CFR §888.3070 Pedicle Screw Spinal System

COMMON NAME: Pedicle Screw Spinal System

PROPRIETARY NAME: VERTEBRON PSS Pedicle Screw System

PREDICATE DEVICES: VERTEBRON PSS Pedicle Screw System (K071376, K051716, K043152 & K033352)

DEVICE DESCRIPTION: The modified VERTEBRON PSS™ Pedicle Screw System is comprised of non-sterile, single use, titanium alloy components. The VERTEBRON PSS™ Pedicle Screw System attaches to the vertebral body by means of screws to the non-cervical spine and allows a surgeon to build a spinal implant construct. This system's design is intended to stabilize the spinal operative site during the fusion process of a bone graft in the disc space. The VERTEBRON PSS™ Pedicle Screw System is made up of rods, multi-axial and standard screws, hooks and locking caps. This submission adds Curved Rods and Screw Spacers.

INTENDED USE: The VERTEBRON PSS™ Pedicle Screw System is intended for non-cervical, non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients. The VERTEBRON PSS™ Pedicle Screw System is intended for non cervical pedicle fixation for the following indications: spondylolisthesis (Grade 3 and 4 at L5-S1 or degenerative

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spondylolisthesis with objective evidence of neurologic impairment); trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

MATERIALS: The material used is titanium Alloy material that conforms to ASTM F136.

SUBSTANTIAL EQUIVALENCE:

Testing in accordance with ASTM F1717 was performed and demonstrated that the modified VERTEBRON PSS Pedicle Screw System is substantially equivalent to the currently marketed VERTEBRON PSS Pedicle Screw System (K071376, K051716, K043152 & K033352).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vertebron, Inc.
% Mr. Luis Nesprido
400 Long Beach Boulevard
Stratford, CT 06615

Re: K081597
Trade/Device Name: VERTEBRON PSS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, KWP, KWQ
Dated: June 3, 2008
Received: June 6, 2008

Dear Mr. Nesprido:

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) 638-2041or (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

4. Indications for Use Statement

510(k) Number (if known): k081597

Device Name: VERTEBRON PSS Pedicle Screw System

Indications For Use:

The VERTEBRON PSS™ Pedicle Screw System is intended for non-cervical, non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients. The VERTEBRON PSS™ Pedicle Screw System is intended for non cervical pedicle fixation for the following indications: spondylolisthesis (Grade 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment); trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use: ___X_____ AND / OR Over-The-Counter Use: _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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

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