K042635
Page 1 of 1

JAN 10 2005

510(k) Summary
for the
Denali Spinal System

This safety and effectiveness summary for the Denali Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, LLC
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :
Richard W. Woods
K2M, LLC
751 Miller Drive SE, Suite F1
Leesburg, VA 20175
Telephone: 703-777-3155

Date Prepared: September 24, 2004

2. Tradename: Denali Spinal System
Common Name: Spine Fixation System
Classification Name: Pedicle Screw Spinal System (21 CFR 888.3070(b)(1))
Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050)

3. Predicate or legally marketed devices which are substantially equivalent :

- Xia Spine System (Stryker Howmedica Osteonics)
- Global Spine Fixation System (U & I Corporation)
- CD Horizon Spinal System (Medtronic Sofamor Danek)

4. Description of the device :

The Denali Spine System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, locking set screws, hooks, and transverse connectors. All of the components are available in a variety of sizes to match more closely the patient's anatomy.

Materials: The devices are manufactured from Ti6Al-4V ELI alloy per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of spinal segments of the thoracic, lumbar and / or sacral spine.

5. Intended Use:

The Denali Spinal System is a non-cervical spinal fixation device intended for posterior, non-pedicle fixation for the following indications: degenerative disc disease (DDD) (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.

The Denali Spinal System is also intended for non-cervical pedicle screw fixation for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The Denali Spine System was biomechanically tested and compared to the predicate systems and other currently marketed systems and performed equal to or better than these systems in ASTM testing to F1717. The design features and sizing of the components were also compared and the Denali System found to be substantially the same as these systems. It is manufactured from the same FDA recognized materials and is indicated for the same intended uses as these systems. There are no significant differences between the Denali Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2005

Mr. Richard W. Woods
Senior Vice President
K2M, LLC
751 Miler Drive SE, Suite F1
Lessburg, VA 20175

Re: K042635
Trade/Device Name: Denali Spine System
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; pedicle screw system
Regulatory Class: Class II
Product Code: KWP, MNH, MNI
Dated: September 24, 2004
Received: September 28, 2004

Dear Mr. Woods:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042635

Device Name: Denali Spinal System

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use __
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K042635