Summary of Safety and Effectiveness
for the
Pyrenees Cervical Plate System

This safety and effectiveness summary for the Pyrenees Cervical Plate 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,
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Leesburg, VA 20175

Date Prepared: February 14, 2006

Contact Person :

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

2. Tradename: Pyrenees Cervical Plate System
Common Name: Anterior Cervical Plate
Classification Name: Spinal Intervertebral Body Fixation Orthosis (888.3060)

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

- Cervical Spine Locking Plate System (Synthes)
- Tectonic Cervical Plate System (K2M, LLC)
- PEAK Anterior Cervical Plate System (Depuy Acromed)

4. Description of the device:

The Pyrenees Cervical Plate System is a spinal fixation system which consists of cervical screws and plates. 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 Commercially Pure Titanium and titanium alloy per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of cervical segments of the spine.

5. Intended Use:

The Pyrenees Cervical Plate System is indicated for use in anterior screw fixation to the cervical spine (C2 – C7) for the following indications : degenerative disc disease (DDD), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).

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

There are no significant differences between the Pyrenees Cervical Plate 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.

510(k): **K060442**

Device Name : **Pyrenees Cervical Plate System**

Indications For Use :

Indicated for use in anterior screw fixation to the cervical spine (C2 – C7) for the following indications: degenerative disc disease (DDD), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).

Prescription use __X__ OR Over-the-counter use _____
(PER 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2006

Mr. Richard W. Woods
Senior Vice President
K2M, LLC
751 Miller Drive SE, Suite F-1
Leesburg, VA 20175

Re: K060442
Trade/Device Name: Pyrenees Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation System
Regulatory Class: II
Product Code: KWQ
Dated: February 15, 2006
Received: February 23, 2006

Dear Mr. Harris:

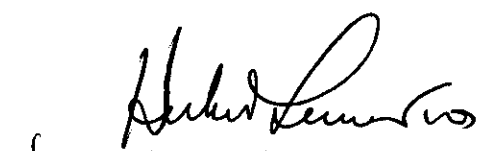
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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" (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 (301) 443-6597 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

510(k): **K060442**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060442