510(k) Summary
Quantum Vertebral Body Replacement

510(k) Number K062004

AUG 15 2006

Manufacturer Identification

Submitted by:
Quantum Orthopedics, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-0121

Contact Information:
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Regulatory Affairs Specialist
Quantum Orthopedics, Inc.
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Date Prepared: July 14, 2006

Device Indentification

Proprietary Name: Quantum Vertebral Body Replacement

Common Name: Vertebral Body Replacement

Classification Name: Spinal Vertebral Body Replacement

Predicate Devices

The subject device is substantially equivalent to the previously cleared Quantum Vertebral Body Replacement.

Device Description

The Quantum Vertebral Body Replacement is a generally box-shaped device with various holes located throughout its geometry. The exterior surface of the device has teeth to help keep the device from migrating once placed in its desired location. It is available in a multitude of sizes to suit the individual pathology and anatomic condition of the patient. The device may be made from titanium or polyetheretherketone (PEEK).

Intended Use of the Device

The Quantum Vertebral Body Replacement is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft.

Performance Data

Mechanical testing indicates that the Quantum Vertebral Body Replacement is capable of performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2006

Quantum Orthopedics, Inc.
c/o Ms. Kerri DiMartino, Regulatory Affairs Specialist
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010

Re: K062004
Trade Name: Quantum VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: July 14, 2006
Received: July 17, 2006

Dear Ms. DiMartino:

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,

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

510(k) Number (if known): K062004

Device Name: Quantum Vertebral Body Replacement

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MXM

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

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