K071372

Tab VIII 510(k) Summary

JUN 11 2007

Sponsor:	RSB Spine, LLC 3030 Superior Ave., Suite 703 Cleveland, OH 44114
Contact Person:	James M. Moran, D. Eng. Vice President of Engineering and Chief Technical Officer
Proposed Trade Name:	InterPlate™ GC VBR
Classification Name	888.3060 – Spinal Intervertebral Body Fixation Orthosis
Device Product Code:	MQP
Device Description:	The InterPlate™ GC VBR System consists of plates, bone screws and screw covers. Various plate sizes are available to accommodate individual patient anatomy and graft material size. Screw covers are individually matched to the plate size.
Intended Use:	The InterPlate™ GC VBR device is indicated for the replacement of a complete or partial vertebrectomy, when used with a bone graft to facilitate fusion. It is designed to restore biomechanical integrity of the thoracic and lumbar spine, from T1 to L5, which has been damaged due to a collapsed or unstable vertebral body resulting from a tumor or traumatic injury.
Materials:	The InterPlate™ GC VBR System components are manufactured from Ti-6Al-4V titanium alloy (ASTM F136).
Substantial Equivalence:	Documentation was provided which demonstrated the InterPlate™ GC VBR to be substantially equivalent to the previously cleared InterPlate™ VBR. The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites, performance and material of manufacture.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RSB Spine, LLC
% Mr. James Moran
Vice President, Engineering
2530 Superior Avenue, Suite 703
Cleveland, Ohio 44114

JUN 11 2007

Re: K071372
Trade/Device Name: InterPlate™ GC VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: May 14, 2007
Received: May 16, 2007

Dear Mr. Moran:

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 toll-free number (800) 638-2041 or (240) 276-3150 or at 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

Tab II Indications for Use

510(k) Number: k071372

Device Name: **InterPlate ™ GC Vertebral Body Replacement (VBR) System**

Indications for Use:

The InterPlate™ GC VBR device is indicated for the replacement of a complete or partial vertebrectomy, when used with a bone graft to facilitate fusion. It is designed to restore biomechanical integrity of the thoracic and lumbar spine, from T1 to L5, which has been damaged due to a collapsed or unstable vertebral body resulting from a tumor or traumatic injury.

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)

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

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