K052533

NOV - 3 2005

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	SIGNUS Medizintechnik GMBH Brentanostra 9 Alzenau, Germany D-63755
Contact Person:	Tracy L. Gray RN, BS, RAC Principal Consultant Alquest, Inc Ph: 763-588-9873 Fax: 763-287-3836 tracyg@alquest.com
Date Prepared:	09-August-2005
Trade Name:	KIMBA™
Classification Name/Number:	Vertebral Body Replacement 21 CFR 888.3060
Product Code:	MQP
Predicate Device(s):	Curved PEEK TETRIS™ cleared under K041888; the RABEA™ cleared under K043316; and the PEEK Tetris™ cleared under K031757.
Device Description:	The KIMBA™ is a hollow, curved frame spinal implant with tapered edges. The upper and lower aspects of the implant are open and the walls feature spikes and ridges which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies. The KIMBA®implant is available in a variety of sizes. This enables the surgeon to choose the size suited to the individual pathology and anatomy and condition and will be implanted individually.
Intended Use:	The KIMBA™ Spinal Implant is intended for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the lumbar spine and is intended for use with supplemental internal fixation. The KIMBA™ is intended to be implanted singularly. The supplemental internal fixation systems that may be used with the KIMBA™ spinal implant include, but are not limited to, SIGNUS Coklusion rod system, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss, TiMX, and Profile).
Functional and Safety Testing:	Design verification tests were performed in compliance with the FDA Guidance document issued May 3, 2004 titled Guidance for Industry and FDA Staff Spinal System 510(k)s. Testing on the subject device included compression, torsion, and expulsion testing.
Conclusion:	SIGNUS GMBH considers the KIMBA™ to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2005

Signus Medizintechnik GMBH
c/o Tracy L. Gray
Principal Consultant
Alquest, Inc.
4050 Olson Memorial Highway, Suite 350
Minneapolis, Minnesota 55422

Re: K052533
Trade/Device Name: KIMBA™ Spinal Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: August 9, 2005
Received: September 15, 2005

Dear Ms. Gray:

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
Acting 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): K052533

Device Name: KIMBA™ Spinal Implant

Indications for Use:

The KIMBA™ Spinal Implant is intended for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the lumbar spine and is intended for use with supplemental internal fixation. The KIMBA™ is intended to be implanted singularly.

The supplemental internal fixation systems that may be used with the KIMBA™ spinal implant include, but are not limited to, SIGNUS Coklusion rod system, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss, TiMX, and Profile).

Prescription Use ___X__ **Or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052533