K122317

8. 510(k) Summary

AUG 29 2012

Date:	30 July 2012
Sponsor:	SIGNUS Medizintechnik GmbH Industriestrasse 2 D-63755 Alzenau, GERMANY Tel. + 49 (0) 6023 9166-136 Fax + 49 (0) 6023 9166-161 Url: http://www.signus-med.de
Contact Person:	Joachim Schneider, Quality Management/Regulatory Affairs
Trade Names:	TETRIS™ II
Device Classification	Class II
Classification Name:	Spinal vertebral body replacement device; Intervertebral fusion device with bone graft, lumbar
Regulation:	888.3060; 888.3080
Device Product Codes:	MQP; MAX
Device Description:	The basic shape of the TETRIS™ II devices is a hollow structural frame having a rounded, tapered leading face. The upper and lower aspects of the implant are open. Surface spikes assist in the positive anchorage and seating of the implant between the vertebral bodies. The device is available in a variety of sizes and angulations thereby enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.
Intended Use:	When used as a vertebral body replacement, the TETRIS™ II devices are indicated 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 thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. When used as an intervertebral fusion device, the TETRIS™ II devices are intended for use at one level in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.
Materials:	The TETRIS™ II devices are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136 or polyetheretherketone (PEEK-OPTIMA® LT1, Invibio®) as described by ASTM F2026. Integral marker pins used in the PEEK devices are manufactured from tantalum as described by ASTM F560.
Predicate Devices:	Titanium TETRIS™ (K022793) PEEK TETRIS™ (K031757) PEEK and Titanium TETRIS™ (K111792)

Technological Characteristics:	The TETRIS™ II devices possess the same technological characteristics as the predicate devices. These include: • intended use (as described above), • basic design (hollow structural frame), • material (PEEK polymer and/or titanium alloy), and • sizes (widths, lengths and heights are within the range(s) offered by the predicate). Therefore the fundamental scientific technology of the TETRIS™ II devices is the same as previously cleared devices.
Performance Data:	Finite element analysis simulations of the worst case TETRIS™ and TETRIS™ II devices were compared. The simulations included those prescribed by ASTM F2077 (compression, torsion and compression shear). The results demonstrate that the additional TETRIS™ II devices do not create a new worst case device. Hence these devices are as safe and as effective as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 29 2012

Sigmus Medizintechnik GMBH
% Backroads Consulting
Karen E. Warden Ph.D.
President
PO Box 566
Chesterland, Ohio 44026-2141

Re: K122317
Trade/Device Name: TETRIS™ II devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: July 30, 2012
Received: August 01, 2012

Dear Dr. Warden:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

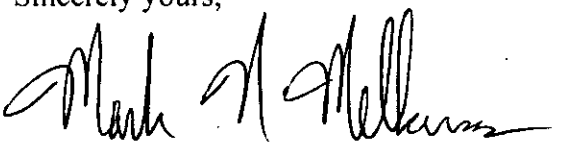
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Indications for Use Statement

510(k) Number: K122317

Device Name: TETRIS™ II devices

Indications for Use:

When used as a vertebral body replacement, the TETRIS™ II devices are indicated 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 thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.

When used as an intervertebral fusion device, the TETRIS™ II devices are intended for use at one level in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.

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 Surgical, Orthopedic,
and Restorative Devices

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