JAN 14 2014

510(k) Summary

Date:	30 November 2012
Sponsor:	SIGNUS Medizintechnik GmbH Industriestrasse 2 D-63755 Alzenau, GERMANY Tel. + 49 (0) 6023 9166-0 Fax + 49 (0) 6023 9166-161 Url: http://www.signus-med.de
Contact Person:	Joachim Schneider, Quality Management/Regulatory Affairs
Trade Names:	TASMIN® R
Device Classification	Class II
Classification Name:	Spinal intervertebral body fixation orthosis; Intervertebral body fusion device
Common Name:	Vertebral Body Replacement Device; Interbody Fusion Device
Regulation:	888.3060; 888.3080
Device Product Codes:	MQP; MAX
Device Description:	The basic shape of the TASMIN® R devices is a hollow structural frame having a rounded, tapered leading face. The upper and lower aspects of the implant are open with peaked teeth that assist in anchoring and seating the implant between the vertebral bodies. There are lateral fenestrations for bony in-growth. 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 TASMIN® R 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 TASMIN® R 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 TASMIN® R devices are manufactured from 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:

PEEK TETRIS™ (SIGNUS – K031757, K111792)
MC+ (LDR Spine USA – K043479)
Hourglass (Medtronic Sofamor Danek – K033926)
Ray TFC (Surgical Dynamics – P950019)
CoRoent® (NuVasive Inc. – K071795)
Capstone Control (Medtronic Sofamor Danek – K120368)

Performance Data:

Finite element analysis simulations of the worst case TETRIS™ and TASMIN® R devices were compared. The simulations included those prescribed by ASTM F2077 (compression, torsion and compression shear).

Static and dynamic compression testing of the worst case TASMIN® R devices was performed according to ASTM F2077. In addition, the subsidence properties were evaluated according to ASTM F2267.

The results demonstrated that the TASMIN® R device performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The TASMIN® R devices possess the same technological characteristics as the predicate devices. These include:

- performance (as described above),
- basic design (hollow structural frame),
- material (PEEK polymer and tantalum), and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate).

Therefore the fundamental scientific technology of the TASMIN® R devices is the same as previously cleared devices.

Conclusion:

The TASMIN® R devices possess the same intended use and technological characteristics as the predicate devices. Therefore the TASMIN® R is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 14, 2014

SIGNUS Medizintechnik GmbH
% Karen Warden, Ph.D.
President
BackRoads Consulting, Incorporated
P.O. Box 566
Chesterland, Ohio 44026-2141

Re: K123758
Trade/Device Name: TASMIN® R
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP, MAX
Dated: November 19, 2013
Received: November 21, 2013

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 contact 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. 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,

Lori A. Wiggins

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

Enclosure

7. Indications for Use Statement

510(k) Number: K123758

Device Name: TASMIN® R

Indications for Use:

When used as a vertebral body replacement, the TASMIN® R 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 TASMIN® R 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)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices