K110153

OCT 1 2 2011

510(k) Summary

Manufacturer:	Königsee Implantate GmbH OT Aschau, Am Sand 4, 07426 Allendorf - GERMANY
Dated Prepared:	January 10, 2011
Device Trade Name:	Spinal Fusion Carrier (SFC™) VBR
Contact:	Justin Eggleton Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Office: 202.552.5800 Fax: 202.552.5798
Classification:	21 CFR §888.3060
Class:	II
Product Code:	MQP

Indications For Use:
SFC™ has been designed to be used in the thoracolumbar spine (T1 to L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). SFC™ is intended to be used with supplemental spinal fixation systems that are cleared by the FDA for use in thoracic and/or lumbar spine such as posterior pedicle screw and rod system, anterior plate systems, and anterior screw and rod systems. The SFC™ may be used with autograft or allograft.

Device Description:
The SFC™ acts as an expandable spacer to maintain proper vertebral body spacing and angulation following vertebrectomy. The SFC™ VBR is manufactured from Ti6Al4V.

Predicate Device(s):
The SFC™ was shown to be substantially equivalent to previously cleared devices (Innovotec SEC VBR, K091743; Aesculap Hydrolift VBR, K083186; Synthes Synex II, K061891) and has the same indications for use, design, function, and materials used.

Performance:
Testing performed on this device indicates that the SFC™ is substantially equivalent to predicate devices. ASTM F2077 and ASTM F2267 performance standards (static axial compression, static axial torsion, static compression shear, dynamic axial compression,

dynamic axial torsion, subsidence, and expulsion) were adhered to and all applicable requirements were met.

Conclusions:
The subject and predicate devices share the same indications for use, design, function, and materials of manufacture. The non-clinical test results demonstrate that any minor differences do not impact device performance as compared to the predicates. The AccuLIF Cage was shown to be substantially equivalent to the cited predicate devices.

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

OCT 12 2011

Konigsee Implantate GmbH
% Musculoskeletal Clinical
Regulatory Advisers, LLC
Mr. Justin Eggleton
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: K110153
Trade/Device Name: Konigsee Implantate Spinal Fusion Carrier (SFC™) VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: September 26, 2011
Received: September 27, 2011

Dear Mr. Eggleton:

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.

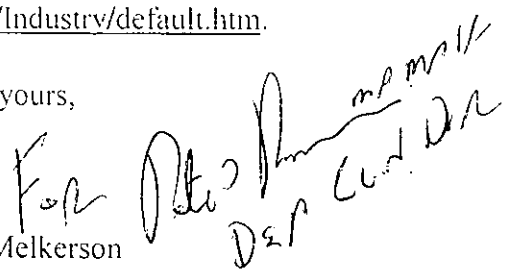
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indications for Use

510(k) Number (if known): K110153

Device Name: **Königsee Implantate Spinal Fusion Carrier (SFC™) VBR**

SFC™ has been designed to be used in the thoracolumbar spine (T1 to L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). SFC™ is intended to be used with supplemental spinal fixation systems that are cleared by the FDA for use in thoracic and/or lumbar spine such as posterior pedicle screw and rod system, anterior plate systems, and anterior screw and rod systems. The SFC™ may be used with autograft or allograft.

Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110153