510(k) Summary:

JUL 2 2 2011

Company:	Eisertech, LLC San Diego, California 92103
Contact:	Lukas Eisermann lukas@eisertech.com 888-262-2817x101
Trade Name:	Cervical Cage
Common Name: Cervical	Intervertebral FusionDevice with Bone Graft,
Classification Name:	Orthosis, spinal intervertebral fusion
Regulation Number:	888.3080
Product Code:	ODP

Substantial Equivalence

Eisertech, LLC believes that the Eisertech, LLC Cervical Cage is substantially equivalent to the Aesculap CeSpace PEEK Spinal Implant System (k083311), the Spinal Elements Crystal Cervical Interbody System (k073351), the Signus Medical, LLC Rabea implant (k082848), the Nuvasive CoRoent-S (k081611), and the Alphatec Spine, Inc. Novel Cervical Spine System (k081730).

Description of device and its intended use

The Cervical Cage is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be packed with autogenous bone graft. The Cervical Cage is intended to be used with a supplemental fixation system.

Description of device design requirements

The Cervical Cage design must maintain the spacing between two vertebral bones following cervical discectomy until fusion occurs.

Identification of the risk analysis method

Risks were qualitatively summarized and addressed by quantitatively analyzing specific in-vivo device performance requirements. The biomechanical loads that the device is expected to be subjected to were described and used as design input criteria. Test results relative to those loading conditions (e.g. design output data) were compared to the design input criteria. The device output data showed

performance meeting or exceeding the design input requirements for all conditions.

Discussion of the device characteristics

The Cervical Cage is an intervertebral body fusion orthosis intended to be used in cervical spinal fusion surgery. It provides mechanical support to the spine and protects the bone graft from excessive loads so that bone healing can occur.

Description of the performance aspects

The Cervical Cage was tested by the methods described in ASTM F2077, including static axial compression, dynamic axial compression, static torsion, and dynamic torsion. Testing per ASTM F2267 to quantify the potential for device subsidence was also conducted. The resistance to expulsion was evaluated by performing expulsion testing against grade 15 polyurethane foam with 100 N axial preload.

The Cervical Cage performs at least as safely and effectively as a legally marketed predicate device.

Reliance on standards

Standards relevant to the methods in which the testing was conducted were relied upon. These include ASTM F2077 and ASTM F2267. However, no performance standard exists for intervertebral body fusion orthoses.

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

Eisertech, LLC
% Mr. Lukas Eisermann
2555 Front Street
San Diego, California 92103

JUL 22 2011

Re: K110915
Trade/Device Name: Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 29, 2011
Received: June 30, 2011

Dear Mr. Eisermann:

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

510(k) Number (if known):

Device Name: Cervical Cage

Indications for Use:

The Cervical Cage is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be packed with autogenous bone graft. The Cervical Cage is intended to be used with a supplemental fixation system.

Prescription Use ✓ AND/OR Over-the-counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ____ of _____

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

510(k) Number K110915