510(k) Summary:

Date: August 29, 2012

AUG 30 2012

Company:

Eisertech, LLC
1133 Columbia Street
Suite 107
San Diego, California 92101

Contact:

Lukas Eisermann
lukas@eisertech.com
888-262-2817x101

Type of 510(k) submission: Special

Trade Name: Cervical Cage

Common Name: Intervertebral FusionDevice with Bone Graft, Cervical

Classification Name: Orthosis, spinal intervertebral fusion

Regulation Number: 888.3080

Device Classification: Class II

Product Code: ODP

Purpose of the Submission

The purpose of this special 510(k) is to change the material of the marker pins from titanium to tantalum, per ASTM F560.

Description of device

The Cervical Cage is offered in a variety of heights, widths, and lengths. The implants are manufactured from medical grade polyetheretherketone (PEEK). Tantalum pins are embedded in the implants to help allow for radiographic visualization.

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.

Materials

The devices are manufactured from medical grade PEEK (ASTM F2026) with tantalum radiographic markers (ASTM F560)

Predicate Devices

Eisertech, LLC Cervical Cage (k110915)
Nexxt Spine Honour Spacer System (k120345)

Technological Characteristics

The Cervical Cage geometry is unchanged from that approved in k110915. The main material of construction, PEEK is unchanged from that approved in k110915. The marker pin material is identical to that used in k120345.

Performance Data

The change in marker pin material does not affect the performance of the product. No additional testing or analysis is provided.

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 30 2012

Eisertech, LLC
% Mr. Lukas Eisermann
Chief Executive Officer
1133 Columbia Street
San Diego, California 92101

Re: K122444
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: August 08, 2012
Received: August 10, 2012

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): K122444

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 ___X___ 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)

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

510(k) Number K122444