K113170

510(k) Summary (April 5, 2012):

APR - 6 2012

Company:	Eisertech, LLC San Diego, California 92103
Contact:	Lukas Eisermann lukas@eisertech.com 888-262-2817x101
Trade Name:	Cervical Plate
Common Name:	Anterior Cervical Plate
Classification Name:	Anterior cervical system
Regulation Number:	888.3060
Product Code:	KWQ

Substantial Equivalence

Eisertech, LLC believes that the Eisertech, LLC Cervical Plate is substantially equivalent to the Blackstone Medical, Inc. Anterior Cervical Plate System (k974885) and the Synthes CSLP System (k926453).

Description of device

The Cervical Plate spinal internal fixation device made from titanium alloy (all components are made from ASTM F-136). It is provided in a variety of sizes ranging from 20mm to 110mm in length, and accommodating fusion of one to four levels of the cervical spine. Two screws may be affixed to each vertebral body associated with the spinal fusion.

All plates, regardless of length have a nominal thickness of 1.85mm and width of 18mm. Screws are provided in 4.0mm and 4.5mm diameters and in fixed and variable angle styles.

Screws are prevented from backing out of the plate by attaching a separate locking mechanism. The mechanism is either a lock washer, consisting of a set screw attached to a washer, or a lock cover, which is a solid screw whose head captures both bone screws at the level of application.

Indications for Use

The Cervical Plate is intended for anterior screw fixation to the cervical spine (C2-C7) *for immobilization and stabilization as an adjunct to fusion in skeletally mature patients* for the following indications:

- Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

- Spondylolisthesis
- Fracture
- Spinal stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudoarthrosis
- Deformity (i.e. kyphosis, lordosis, and/or scoliosis).

Description of device design requirements

The Cervical Plate must stabilize the spine while fusion occurs. It must keep the fused vertebrae in their intended alignment.

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 Plate is an anterior cervical spinal plate intended to be used in cervical spinal fusion surgery. It provides internal fixation to the spine and protects the bone graft from excessive loads so that bone healing can occur.

Description of the performance aspects

The Cervical Plate was tested by the methods described in ASTM F1717, including static axial compression, dynamic axial compression, and static torsion. Mechanical performance in each tested mode was equivalent or superior to previously marketed devices.

Comparison of Technological Similarities or Differences to Predicate Devices

The Cervical Plate utilizes the same basic technology as its predicate. Both systems are titanium alloy plates of similar size and shape. Both plate systems provide fixed and variable angle screws of 4.0 and 4.5mm diameter. The plates have similar thicknesses, widths, general geometry, and mechanical performance.

Reliance on standards

Standards relevant to the methods in which the testing was conducted were relied upon. This includes ASTM F1717. However, no performance standard exists for anterior cervical spinal plates.

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

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

APR - 6 2012

Re: K113170
Trade/Device Name: Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 1, 2012
Received: March 2, 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

K113170

510(k) Number (if known): K113170

Device Name: Cervical Plate

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

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