K080646

MAY - 2 2008

BIOMET SPINE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054

Establishment Registration Number:
2242816

Contact:
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Date Prepared:
April 30, 2008

Trade/Proprietary Name:
C-Tek® MaxAn™ Anterior Cervical Plate System

Common/Usual Name:
Spinal intervertebral body fixation orthosis

Classification Name:
Appliance, Fixation,Spinal Intervertebral Body

Device Classification:
Class II, 21 CFR §888.3060, KWQ

Predicate Device(s):
EBI Anterior Cervical Plate System (Cyprus Anterior Cervical Plating System), K060379
EAGLE+ Anterior Cervical Plate system, K070994, K040197
Swift Plus Anterior Cervical Plate System, K072546, K040655

Device Description:
The C-Tek® MaxAn™ Anterior Cervical Plate System consists of titanium alloy plates and screws. Screws are provided in both fixed and variable versions in sizes 4.0 mm and 4.5 mm with lengths from 8-26 mm. Screws will be provided in both sterile and non-sterile configurations.
Cervical plates are provided in both sterile and non-sterile configurations for 1 – 6 levels and in appropriate lengths from 8-150 mm.

Indications for Use:
The C-Tek® MaxAn™ Anterior Cervical Plate System is intended for anterior interbody fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during

the development of cervical fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses, and/or failed previous fusions. The intended levels for treatment range from C2 – T1.

Materials:

The C-Tek® MaxAn™Anterior Cervical Plate System is comprised of various sizes of plates and screws made from titanium alloy (Ti-6Al-4V, ASTM F-136)

Performance:

The technological characteristics of the C-Tek® MaxAn™ Anterior Cervical Plate System are the same as, or similar to, the predicate devices. Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the devices are functional within the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Biomet Spine
% Jacqueline A. Hughes, RAC
Vice President, Quality/Clinical/Regulatory Affairs
100 Interpace Parkway
Parsippany, NJ 07054

Re: K080646
Trade/Device Name: C-Tek® MaxAm™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 5, 2008
Received: March 6, 2008

Dear Ms. Hughes:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080646

Device Name: C-Tek® MaxAn™ Anterior Cervical Plate System
Indications for Use:

The C-Tek® MaxAn™ Anterior Cervical Plate System is intended for anterior interbody fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during the development of cervical fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses, and/or failed previous fusions. The intended levels for treatment range from C2 – T1.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080646