FEB 4 2000

K994383

Dogbone ACFS

510 (k) Summary

Company: Theken Surgical
1100 Nola Avenue
Barberton, Ohio 44203

Trade Name: Dogbone ACFS

Classification: KWQ 888.3060, Spinal Intervertebral Body Fixation Orthosis. Class II.

Description: The Dogbone ACFS is a titanium alloy anterior cervical plate fixation system. Plates are pre-contoured in two planes, and come in a variety of lengths. Screws are available in two diameters, several lengths, and two different styles; fixed angle and variable angle. Fixed angle screws are used to build a rigid fixation construct. Variable angle screws are used to build a non-rigid construct. Hybrid constructs combining elements of fixed and variable angle screws may be built also. Eight locking fingers circumferentially disposed around the rim of each screw hole engage the screw heads to provide mechanical resistance against screw back-out.

Performance Data:

Non-clinical:

Static and fatigue cantilever axial compression testing was performed. Properties of stiffness, strength, and fatigue life were characterized. Static torsion was also examined.

Intended Use:

The Dogbone ACFS is indicated for:

The Dogbone ACFS is indicated for trauma, deformity (lordosis and kyphosis), pseudoarthrosis, previously failed cervical spine fusion, tumor, degenerative disk disease (DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.), and spinal canal stenosis.

The Dogbone ACFS is indicated for stabilizing the spine from C2 to C7. Unicortical or bicortical fixation from the anterior face of the vertebral bodies may be employed using either the variable angle or fixed angle screws. This product may be employed as an internal fixation device during the time interval required for arthrodesis.

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Substantial Equivalence:

Synthes (USA) Titanium Locking Plate System (TILPS) (K970048)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Mr. Lukas Eisermann
Director, Regulatory Affairs
Theken Surgical
1100 Nola Avenue
Barberton, Ohio 44203

Re: K994383
Trade Name: Dogbone ACFS
Regulatory Class: II
Product Code: KWQ
Dated: December 27, 1999
Received: December 28, 1999

Dear Mr. Eisermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R.P. Ogden for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known):

Device Name: Dogbone ACFS

1. Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1/2/96)

DRO for JZD
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994383