K042798
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510(k) SUMMARY

SUBMITTED BY

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This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Spinal intervertebral body fixation orthosis
Common/Usual Name:	Appliance, Fixation, Spinal Intervertebral Body
Product Classification:	21 CFR §888.3060, Class II
Product Code:	KWQ
Proprietary Name:	C-TEK C-Thru Anterior Cervical Plate System

PREDICATE DEVICE

Predicate device information is included in this premarket notification.

INDICATIONS-FOR-USE

The C-TEK C-Thru Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in the temporary stabilization of the anterior spine from C_2 to C_7 during the development of cervical spinal fusions in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures); primary and metastatic malignant tumors; deformity (defined as kyphosis, lordosis, or scoliosis); pseudarthrosis; failed previous fusions; and/or spinal cord stenosis and cervical myelopathy.

DEVICE DESCRIPTION

The C-TEK C-Thru Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates and screws manufactured from surgical implant grade titanium alloy as described by ASTM F 136 (Ti 6Al 4V ELI). The plates are provided in a fixed hole or slotted hole design and are available in 1 to 5 level plates. The screws are supplied color coded to identify their respective lengths. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

NOTE: This device system is intended for anterior cervical intervertebral body fusion only.

COMPARISON TO THE PREDICATE DEVICE

Based on the same indications for use, intended use, similarity in materials of construction and equivalent biomechanical performance, the C-TEK C-Thru Anterior Cervical Plate is considered substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2004

Ms. Wendy Spielberger
Lead Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K042798
Trade/Device Name: C-TEK C-Thru 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: October 7, 2004
Received: October 8, 2004

Dear Ms. Spielberger:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
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): K042798

Device Name: **C-TEK C-Thru Anterior Cervical Plate System**

Indications-For-Use:

The INTERPORE CROSS C-TEK C-Thru Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in the temporary stabilization of the anterior spine from C_2 to C_7 during the development of cervical spinal fusions in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures); primary and metastatic malignant tumors; deformity (defined as kyphosis, lordosis, or scoliosis); pseudarthrosis; failed previous fusions; and/or spinal cord stenosis and cervical myelopathy.

Prescription Use X **AND/OR** **Over-The-Counter Use**_____
(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)

for Mark N Melkerson

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

510(k) Number K042798