K964159

CD™ SPINAL SYSTEM
510(k) Summary of Safety and Effectiveness
K964159
October 1997

OCT 16 1997

I. Company:

Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
901-396-3133

II. Proposed Proprietary Trade Name: CD™ Spinal System

III. Description:

The CD™ Spinal System consists of rods, hooks, screws, connectors, and cross connectors, and other components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components. The purpose of the CD™ Spinal System is to provide stabilization during the development of a solid spinal fusion.

IV. Indications:

When used as a pedicle screw fixation system with CD screws attached to the non-cervical posterior spine, the CD Spinal System is indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system, the CD Spinal System is also indicated for Grade III and IV spondylolisthesis. For this indication only, the spondylolisthesis must be at L5-S1 in patients who are receiving fusions using autogenous bone graft only and who are having the device removed after the development of a solid fusion mass. Although the levels of fusion may not go above the L5-S1 joint for these severe spondylolisthesis cases, the levels of pedicle screw fixation may be L3 to the sacrum.

When used as a posterior non-pedicle screw fixation system, the CD Spinal System is intended for the indications given above as well as spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), fracture, pseudarthrosis, tumor resection, and unsuccessful previous attempts at spinal fusion. For non-pedicle screw use, the levels of fixation for the CD Spinal System are T1 to sacrum, with the screws limited to sacral fixation.

V. SUBSTANTIAL EQUIVALENCE

The CD™ Spinal System was found to be substantially equivalent to a preamendments device. Bridging data consisting of clinical data, mechanical testing, and theoretical safety profile analyses were provided to substantiate the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard W. Treharne, Ph.D.
Vice President
Research and Regulatory Affairs
Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

OCT 16 1997

Re: K964159
CD™ Spinal System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: July 16, 1997
Received: July 18, 1997

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 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 your device system subject to the general controls provisions of the Act and the limitations identified below. 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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment for indications other than that described in item 2 below, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than that described in item 2 below, is a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package label, must state that there are labeling limitations.

2. The package insert must prominently state that the device system, as a pedicle screw fixation system, is intended only for the following:

   a. degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). For this indication, the system is limited to noncervical screw fixation; and

   b. severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint in patients who are receiving fusions using autogenous bone graft only and who are having the device removed after the development of a solid fusion mass. For this indication, the system is limited to screw fixation from L3 to the sacrum.

3. The package insert must also include the following **WARNINGS:**

   - As a pedicle screw fixation system, this subject system is intended only for the following:

     - degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). For this indication, the system is limited to noncervical screw fixation; and

     - severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint in patients who are receiving fusions using autogenous bone graft only and who are having the device removed after the development of a solid fusion mass. For this indication, the system is limited to screw fixation from L3 to the sacrum.

   - Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

   - Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

4. Any pedicular screw fixation/attachment for intended uses other than that described by item 2 above, for this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment for intended uses other than that described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

5. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of item 3 above.

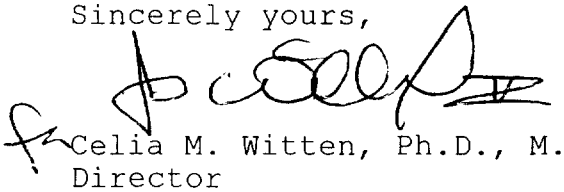
FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required.

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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

October 16, 1997

510(k) Number (if known): K964159

Device Name: CD™ Spinal System

INDICATIONS:

When used as a pedicle screw fixation system with CD screws attached to the non-cervical posterior spine, the CD Spinal System is indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).

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

Concurrence of CDRH, Office of Evaluation (ODE)

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

(Optional 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K964159