

SEP 14 1999

**DANEK® Plate and Screw System  
510(k) Summary**

**March 1999**

- I. **Company:** Sofamor Danek USA  
1800 Pyramid Place  
Memphis, TN 38132  
(901) 396-3133
- II. **Proposed Proprietary Trade Name:** DANEK® Plate and Screw System
- III. **Description**

The DANEK® Plate and Screw System consists of plates, screws, hooks, CROSSLINK® Plates and other components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components. The purpose of the DANEK® Plate and Screw System is to provide stabilization during the development of a solid spinal fusion.

DANEK® Plate and Screw implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. The DANEK® Plate and Screw System implant components may be sold either sterile or non-sterile

IV. **Indications for Use**

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the DANEK® Plate and Screw System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the DANEK® Plate and Screw System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

**V. Substantial Equivalence**

The DANEK® Plate and Screw System is substantially equivalent to itself. The new pedicle screw classification indications described in the classification Final Rule published in the July 27, 1998 Federal Register were used to expand the previously cleared indications for the DANEK® Plate and Screw System. This system is also substantially equivalent to the DYNA-LOK® Spinal System.

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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

Re: K991036

Trade Name: DANEK® Plate and Screw System  
Regulatory Class: II  
Product Code: MNH and MNI  
Dated: June 23, 1999  
Received: June 24, 1999

Dear Dr. Treharne:

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 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.

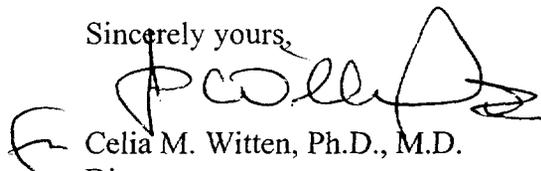
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 Dr. Richard W. Treharne

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,

A handwritten signature in black ink, appearing to read "C. Witten", with a large, stylized flourish at the end.

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

March 1999

510(k) Number (if known): K991036

Device Name: DANEK® Plate and Screw System

**Indications for Use:**

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

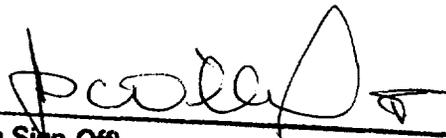
Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional 1-2-96)

  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K991036