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

JUL 30 1997

Re: K963780
Dual Rod Anterior Fixator System
Regulatory Class: II
Product Code: KWQ
Dated: May 22, 1997
Received: May 23, 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 would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, would be found not substantially equivalent and would be 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. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the package insert must include the following statement, "**WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";

2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and

3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system 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 system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

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.

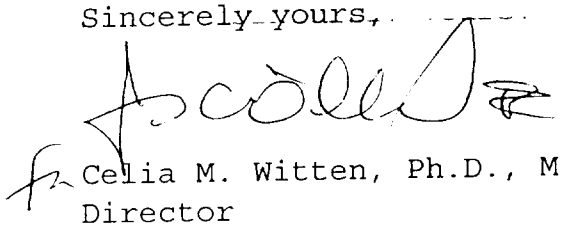
FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical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

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,



for 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

K963780

Dual Rod Anterior Fixator System
510(k) Summary
K963780
May, 1997

JUL 30 1997

I. **Company:** Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
901-396-3133

II. **Proprietary Trade Name:** Dual Rod Anterior Fixator System

Classification Name: Spinal intervertebral body fixation orthosis.

III. The Dual Rod Anterior Fixator System consists of the Dual Rod Fixator, transverse connector, bolts, and nut (DYNA-LOK® nut). Instrumentation is also available to facilitate implantation of the device components. The purpose of the Dual Rod Anterior Fixator System is to provide stabilization during the development of a solid spinal fusion. The Dual Rod Anterior Fixator System implant components are fabricated from ASTM F136 (or its ISO equivalent) titanium alloy or ASTM F138 (or its ISO equivalent) stainless steel and may be sold sterile or non-sterile. Titanium alloy implants are not to be used with stainless steel implant components in a spinal construct

IV. The Dual Rod Anterior Fixator System is designed to aid in the surgical correction and stabilization of the spine. The system is intended to assist stabilization until a solid spinal fusion develops. The specific indications for the Dual Rod Anterior Fixator System are the following:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Pseudoarthrosis
3. Stenosis
4. Spondylolisthesis
5. Spinal deformities: scoliosis, kyphosis, lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

All components of the Dual Rod Anterior Fixator System are intended to be fixed/attached to the anterolateral spine by bolts/prongs in the thoracic and/or lumbar areas only.

V. Mechanical test data were supplied in support of the Dual Rod Anterior Fixator System 510(k) notification. The Dual Rod Anterior Fixator System was declared to be substantially equivalent to several commercially available devices.

510(k) Number (if known): K963780

Device Name: Dual Rod Anterior Fixator System

Indications For Use:

The Dual Rod Anterior Fixator System is designed to aid in the surgical correction and stabilization of the spine. The system is intended to assist stabilization until a solid spinal fusion develops. The specific indications for the Dual Rod Anterior Fixator System are the following:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Pseudoarthrosis
3. Stenosis
4. Spondylolisthesis
5. Spinal deformities: scoliosis, kyphosis, lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

All components of the Dual Rod Anterior Fixator System are intended to be fixed/attached to the anterolateral spine by bolts/connector spikes in the thoracic and/or lumbar areas only.

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

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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K963780