ORION® Anterior Cervical Plate System
510(k) Summary
K973854
January 1998

MAR 16 1998

I. **Company:**

Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Product Name:** ORION® Anterior Cervical Plate System

Classification Name: Spinal intervertebral body fixation orthosis

III. The ORION® Anterior Cervical Plate System consists of a variety of bone plates and screws. Fixation is provided by the insertion of bone screws through the openings at each end of the plate into the vertebral bodies of the cervical spine. The ORION® Anterior Cervical Plate System features a locking screw which screws into each end of the plate to help secure the positioning of the ORION® screws. The use of the locking screw is not optional. In addition, the central portion of ORION® plates have slots and holes which accommodate 4.35mm diameter ORION® screws. The placement of these central screws is intended to augment fixation by providing additional vertebral body purchase and/or bone graft purchase. The use of the central screws is recommended. Associated instruments are also available to facilitate the implantation of the device. The implant components will be made from titanium alloy as described by ASTM F-136 or ISO 5832-3 and may be supplied either sterile or non-sterile.

IV. The ORION® Anterior Cervical Plate System is intended for anterior cervical intervertebral body fusions only. The system is indicated for use in the temporary stabilization of the anterior spine 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), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

V. The ORION® Anterior Cervical Plate System was claimed to be substantially equivalent to commercially available cervical plating systems. Information concerning these devices was supplied in support of establishing equivalence.

Mechanical test data were provided in support of this notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1998

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

Re: K973854
ORION® Anterior Cervical Plate System
Regulatory Class: II
Product Code: KWQ
Dated: January 8, 1998
Received: January 12, 1998

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

October, 1997

510(k) Number (if known): K973854

Device Name: ORION® Anterior Cervical Plate System

Indications For Use:

The ORION® Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine 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), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973854

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

(Optional Format 1-2-96)