

JUN - 7 2000

K993266

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Section 7 - 510(k) Summary of Safety and Effectiveness

7.1 Statement This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

7.2 Submitter Advanced Spine Technology, Inc.
3645 Grand Avenue, Suite 304
Oakland, CA. 94610

7.3 Company Contact Susan Finneran
QA/ RA Manager (Endius, Inc.)
508-643-0983
Acting as a consultant to Advanced Spine Technology, Inc.

7.4 Device Name **Proprietary Name:**
Window Cervical Dynamic Plate System
Common Name:
Anterior Cervical Plating System
Classification Name:
Spinal Intervertebral Body Fixation Orthosis.(KWQ)

7.5 Predicate Legally Marketed Devices ORION Anterior Cervical Plate System manufactured by Sofamor Danek (Memphis, TN.)

**7.6
Device
Description** The Window Cervical Plate System is a set of implants designed to be implanted via an anterior approach to the cervical spine. The system includes various plates and screws manufactured from Titanium. The material used in the manufacture of the components in the Window Cervical System meets ASTM F136 for Ti 6Al-4VELI.

**7.7
Device
Indications and
Intended use** The Window 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), pseudoarthrosis, 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

**7.8
Substantial
Equivalence** The Window Cervical Plate Spinal System is substantially equivalent to the ORION Cervical Spinal System.
Following is a table that describes the features of the new and the predicate systems that indicate substantial equivalence. Testing was also completed as per ASTM F1717 in order to demonstrate equivalence. The results of testing are included in appendix 1 of the submission.

7.9 Table of Substantial Equivalence

Device Name	The Window Cervical Plate Spinal System	ORION Cervical Plate System
Product Components	Plates of various lengths, 4mm screws, 4.3mm revision screws	Plates of various lengths, 4mm screws, 4.35mm revision screws
Indications for Use	See above	Identical
Materials	Titanium	Titanium
Product Labeling	Instructions for use and box labeling including all of the necessary warning statements	Instructions for use and box labeling including all of the necessary warning statements
Packaging/ Sterilization	Non-sterile, single use only	Non-sterile, single use only

Applicant

Susan June

Date

12/13/99



JUN - 7 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gordon Tao
President of Advanced Spine Technology Incorporated
C/O Ms. Susan Finneran
Regulatory Affairs Consultant, AST
QA/RA Manager
Endius Incorporated
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K993066
Trade Name: Window Cervical Dynamic Plate System
Regulatory Class: II
Product Code: KWQ
Dated: March 23, 2000
Received: April 3, 2000

Dear Mr. Tao:

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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

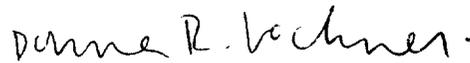
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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.

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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,



 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

510(k) Number (if known): K993066

Device Name: Window Cervical Dynamic Plate System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Donna R. Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993066