

DEC 30 1998

Anterior Cervical Plating System

Summary of Safety and Effectiveness

K984342

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Karen F. Jurczak

DATE PREPARED: December 1, 1998

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis

COMMON NAME: Cervical Bone Plate System

PROPRIETARY NAME: ALINE™ Anterior Cervical Plating System

PREDICATE DEVICES: ALINE™ Anterior Cervical Plating System (K943523)

DEVICE DESCRIPTION: The ALINE™ Anterior Cervical Plating System is utilized to provide post-operative stabilization until fusion of the cervical spine has eventuated. Essentially, the plating system acts as an internal splint that carries a portion of the load until the process of healing is complete.

INTENDED USE: The ALINE™ Anterior Cervical Plating System is designed to provide temporary stability to the cervical spine during the development of a solid spinal fusion in patients with degenerative disc disease (DDD), trauma (including fractures) and tumors. DDD is defined as neck and/or arm pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. The device is intended for anterior cervical intervertebral body screw fixation only.

MATERIALS: The Aline Cervical Plating system consists of Ti-13-13 plates, bone screws, and locking screws.



DEC 30 1998

Ms. Karen F. Jurczak
Associate, Corporate Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K984342

Trade Name: Aline™ Anterior Cervical Plating System
Regulatory Class: II
Product Code: KWQ
Dated: December 2, 1998
Received: December 4, 1998

Dear Ms. Jurczak:

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.

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,

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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,


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

Anterior Cervical Plating System

Indications for Use

510(k) Number (if known): K984342

Device Name: ALINE™ Anterior Cervical Plating System

Indications For Use:

The ALINE™ Anterior Cervical Plating System is designed to provide temporary stability to the cervical spine during the development of a solid spinal fusion in patients with degenerative disc disease (DDD), trauma (including fractures) and tumors. DDD is defined as neck and/or arm pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. The device is intended for anterior cervical intervertebral body screw fixation 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)

Harold J. Ferguson for cmv
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984342