



MAY 27 1998

**510(k) Summary****Top Surgical SIMAL Cervical Stabilization System****1. Submitter's Name, Address and Telephone Number, and Contact Person:**

Miss Karenann J. Brozowski

Top Surgical Products  
c/o TFX Medical Group of Teleflex, Inc.  
Tall Pines Park  
Jaffrey, NH 03452

Telephone Number: (603) 532-7706

Contact Person:  
Karenann J. Brozowski

**2. Name of the Device, including the trade or proprietary name, if applicable, and the common name, and the classification name, if known.**

Trade Name: SIMAL Cervical Stabilization System

Common Name: Spinal Intervertebral Stabilization System

Classification Name: Spinal Intervertebral Body Fixation Orthosis

**3. Identification of the legally marketed device that the submitter claims equivalence.**

The devices in consideration are substantially equivalent to the devices currently marketed by Aesculap, Caspar Anterior Cervical Fusion Instrumentation System, K953720; Synthes Anterior Cervical Vertebrae Plate System, K945700; and Synthes Cervical Vertebrae Plates, K792352.

*A Teleflex Company*

One Weck Drive, P.O. Box 12600  
Research Triangle Park, North Carolina 27709  
(919) 544-8000

**4. A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or the promotional material of the device.**

The SIMAL Cervical Stabilization System are screws and plates for anterior stabilization of the cervical spine and for anterior C2, C1 stabilization from the trans-oral approach.

The anterior stabilization plates have large length varieties with four lengths per segment to fit all patient sizes. For the Trans-oral approach "winged" models secure placement of articular grafts.

Both of the types of plates are anchored by titanium screws, which are available in various sizes.

**5. Statement of intended use of the device that is the subject of the premarket notification submission.**

The intended use of the SIMAL Cervical Stabilization Device is anterior screw fixation of the cervical spine. Fixation is done via ventral or transoral approach.

Indications for Use: Spondylolisthesis(instability), fractures, spinal stenosis, deformities (scoliosis, kyphosis, lordosis), tumors, or pseudarthrosis

**6. If the device has the same technological characteristics as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to the legally marketed device.**

The technological characteristics of the devices are the same. Each of the devices are made of titanium segmented plates and screws with the same characteristic shapes and are anchored by two diameters of titanium screws of various lengths .



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 27 1998

Ms. Karenann J. Brozowski  
Group Regulatory Affairs Director  
Top Surgical Products  
c/o TFX Medical Group of Teleflex, Inc.  
Tall Pines Park  
Jaffrey, New Hampshire 03452

Re: K981008  
SIMAL Cervical Stabilization System  
Regulatory Class: II  
Product Code: KWQ  
Dated: March 17, 1998  
Received: March 18, 1998

Dear Ms. Brozowski:

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.

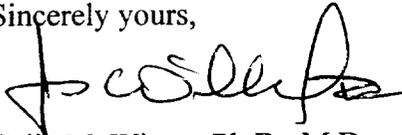
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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,



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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

510(k) Number (if known): K981008

Device Name: SIMAL Cervical Sterilization System

Indications For Use:

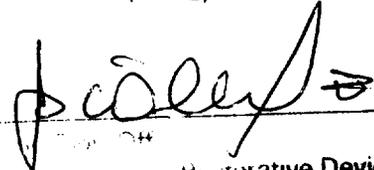
The TSP Cervical Stabilization System is intended for anterior screw fixation to the cervical spine. Fixation is done via ventral or transoral approach.

Indications for Use:

- \* Spondylolisthesis (instability)
- \* Fractures
- \* Spinal Stenosis
- \* Deformities (Scholiosis, Kyphosis, Lordosis)
- \* Tumors
- \* Pseudarthrosis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Date) \_\_\_\_\_  
 Director, Center for Devices and Radiological Controls  
 Division of Restorative Devices  
 510(k) Number K981008

Prescription Use X  
(Per 21 CFR 801.109)

OR

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

(Optional Format 1-2-96)