DEC 27 1999

K990959

4 510(k) Summary [As required by 21 CFR 807.92(c)]

4.1 Submitter Information

Manufacturer's Name & Address
Spineology Group, LLC
1815 Northwestern Avenue
Stillwater, MN 55082

Manufacturer's Contact Person
Pamela Snyder
Director of Clinical & Regulatory Affairs
Phone: 651-351-1011 Fax: 651-351-0712

4.2 Device Names

Proprietary Name:	K-Centrum Anterior Spinal Fixation System
Common/Usual Name:	anterior spinal fixation device
FDA Classification Name:	21 CFR 888.3060, Spinal Intervertebral Body Fixation Orthosis
FDA Classification:	Class II, product code KWQ

4.3 Predicate device

Manufacturer	Device	510(k)	Approved
Sofamor Danek	Z-Plate Anterior Fixation System	K922543	5/19/93

4.4 Device Description

The K-Centrum Anterior Spinal Fixation System is a multi-component system. The construct utilizes all of the following implantable components: Vertebral Body Anchors (Two); Linkage rod (One); Set screws (Two); Locking caps (Two). The K-Centrum System includes unique instrumentation to assist the surgeon in placing the anchors parallel to each other.

4.5 Intended Use

The K-Centrum Anterior Spinal Fixation System is intended for alignment correction and stabilization of the thoracolumbar spine. The K-Centrum is also intended to provide stabilization to augment the development of a solid spinal fusion. The K-Centrum is intended for threaded anchor/ fixation attachment to the anterolateral intervertebral bodies from T10 to L2 only and not more than 2 motion segments. The K-Centrum is indicated for vertebral body fractures and tumors.

4.6 Technological Characteristic Comparisons

In addition to having comparable intended use and indications for use, the K-Centrum Anterior Spinal Fixation System and the Sofamor Danek Z-Plate ATL Anterior Fixation System are substantially similar in design features. Both devices are manufactured from the same titanium alloy (Ti-6Al-4V, ELI), in accordance with the same standard material specification (ASTM F 136 – 96). Both system configurations include anchors, longitudinal elements for linkage, and

locking mechanisms. For safety reasons, the K-Centrum has been designed to be a low-profile implant, to minimize the opportunity for device impingement on soft tissues and vascular structures. Anchors for both systems are secured to the vertebral body by threaded attachment. The details of anchor geometry differ, in part because the Z-Plate utilizes two small diameter anchors in each vertebral body, while the K-Centrum employs a single larger diameter anchor. Both anchor systems provide comparable surface area for direct bone contact. The longitudinal linkage elements are of different configurations. The K-Centrum utilizes a round-cornered rectangular rod, nearly symmetrical in the transverse plane, for linkage; the Z-Plate has a contoured, relatively wide plate, asymmetrical in the transverse plane. Both linkage elements are designed to resist tension, compression, bending, and torsion. In both the K-Centrum and Z-Plate systems, the linkage component is secured to the anchors via a threaded clamping/locking component: a locking nut for the Z-Plate, a set screw and locking cap for the K-Centrum.

4.7 Summary of Testing

Results from comparative mechanical testing results shows that the K-Centrum performs comparably to the Z-Plate, and both devices exceed the minimum performance requirements outlined in the FDA guidance document, "Device Considerations for Spinal Fixation Device Systems", FDA, 1993. The testing included: Static Testing per ASTM 1717-96; Fatigue Testing per ASTM F 1717-96; Interconnection Testing: Set screw to linkage rod; Simulated Use Testing of Anchor Guidance System; and Comparative Anchor Pullout Testing. No new types of safety or effectiveness questions were raised as a result of the testing or risk analysis performed for the K-Centrum Anterior Spinal Fixation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 1999

Ms. Pamela Snyder
Director of Clinical and Regulatory Affairs
The Spineology Group, LLC
1815 Northwestern Avenue
Stillwater, Minnesota 55082

Re: K990959
Trade Name: K-Centrum Anterior Spinal Fixation System
Regulatory Class: II
Product Code: KWQ
Dated: September 28, 1999
Received: September 30, 1999

Dear Ms. Snyder:

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, 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,

Neil R.P. Ogden for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE STATEMENT

510(k) Number (if known): K990959

Device Name:
K-Centrum Anterior Spinal Fixation System

Indications for Use:

The K-Centrum Anterior Fixator is intended for correction and stabilization of the spine. The K-Centrum is also intended to provide temporary stabilization and augment the development of a solid spinal fusion. The K-Centrum is intended for screw/bolt/fixation attachment to the anterolateral intervertebral bodies from T10 to L5 only and less than 4 motion segments.

The K-Centrum is indicated for degenerative disk disease, disk herniation, spondylosis, spondylolisthesis, burst fracture, failed surgery, corpectomy or vertebrectomy for tumor resection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRC for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990959

Prescription Use YES
(Per 21 CFR 801.109)