DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1999

Advanced Spine Fixation Systems, Inc.
c/o Mr. Greg Holland
Holland & Associates
3722 Avenue Saulsalito
Irvine, California 92606

Re: K990845
Trade Name: Modification to K954770 - Varigrip device components numbered CGT-SL and CGT-SL-15
Regulatory Class: II
Product Codes: KWP and MNH
Dated: March 12, 1999
Received: March 15, 1999

Dear Mr. Holland:

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,

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): K990845

Device Name: Verifix System

Indications For Use:

The Varifix System with pedicle screw attachment is only indicated for patients with severe spondylolisthesis, grades 3 and 4, of the fifth lumbar-first sacral (L5-S1) joint. This indication is for those who are receiving fusions using autogenous bone graft only. The Varifix System is to be removed after the development of a solid fusion mass.

The Varifix System with sacral screws and sublaminar wiring and the Varigrip System are intended for treatment of cases of degenerative disc diseases (ddd is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, spinal stenosis, deformities (including scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, and multi-operated back or revision of previous surgery. Other indications include degenerative lumbar scoliosis, degenerative spondylolisthesis, and in spinal stenosis, where decompression is required.

For indication other than severe spondylolisthesis (grade 3 or 4) at the L5-S1 vertebral joint this device in intended for sacral/iliac/lamina attachment only. The attachment points of the sacral screws are intended for the S1 or S2 locations. The sublaminar wire fixation levels range from L1 to L5. To facilitate fusion of the fifth lumbar-first sacral (L5-S1) the attachment points of the pedicle screws are limited to L3, L4, and L5 vertebrae. In addition, the titanium components are also intended for those individuals who have sensitivity to some of the elements present in stainless steel alloys. The Varigrip is intended to be attached to the non-cervical 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 K990845

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)