DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Ms. Carol Freasier
Manager, Regulatory Affairs Quality Assurance
Ortho Development Corporation
106 West Business Park Drive
Draper, Utah 84020

Re: K990986
Trade Name: Contour Spinal System®
Regulatory Class: II
Product Code: KWP and MNH
Dated: July 26, 1999
Received: July 28, 1999

Dear Ms. Freasier:

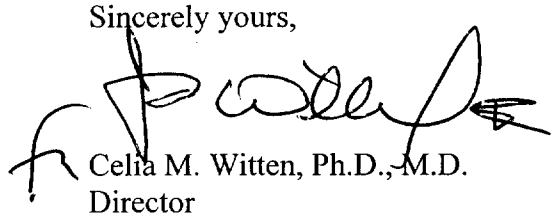
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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 (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

Enclosures

510(k) Number (if known): K990986

Device Name: Contour™ Spinal System

Indications for Use

When used as a pedicle screw fixation system (MNH) The Contour™ Spinal System is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion mass.

Use of a hook, rod, and ileo-sacral screw fixation system (KWP) T1-S1, the Lumbar Hook Sacral Screw Construct of the Contour™ Spinal System, will assist in arthrodesis or fusion of the thoracic, lumbar and lumbosacral spine. The indications for use are:

- Spondylolisthesis;
- Fracture;
- Spinal Stenosis;
- Deformities (scoliosis, kyphosis, lordosis);
- Pseudarthrosis
- Tumor
- Revision of previously failed fusion surgery

The hooks are to be used for fixation to include the first thoracic vertebra down to the sacrum. The pedicle screws are used for sacral fixation only.

(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 K990986

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