K05216 1/2

PREMARKET NOTIFICATION 510(K) SUMMARY

JUL 19 2005

Company:

Director RA/QA
Altiva Corporation
9800 Suite I, Southern Pines Blvd
Charlotte, NC 28273
Telephone: 704/409-1754
Fax: 704/409-1771

Company Contact: John Kapitan

Date: May 10, 2005

Trade Name: HydraLok™ System

Common Name Classification: Pedicle Screw Spinal Fixation System
Orthopedics, 888.3070, Class II
FDA Product Code ; MNI, MNH

Device Description: The HydraLok System is a top-loading spinal fixation system including screws, rods, and connectors. The titanium alloy components are provided clean and non-sterile. Various sizes of the implants are provided.

Intended Use:

The HydraLok System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis)

In addition, when used as a pedicle screw fixation system, the HydraLok System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft only having the device attached to the lumbar and sacral spine (L3 and below), who are having the device removed after the development of a solid fusion.

Predicate Device: Predicate device information is included.

Performance Data: Performance data were submitted to characterize the HydraLok System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2005

Mr. John Kapitan
Director RA/QA
Altiva Corporation
9800-I Southern Pine Boulevard
Charlotte, North Carolina 28273

Re: K051216
Trade/Device Name: Altiva HydraLok™ System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: May 10, 2005
Received: May 12, 2005

Dear Mr. Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): _____

Device Name: Altiva HydraLok™ System

Indications for Use:

The HydraLok System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

- degenerative spondylolisthesis with objective evidence of neurological impairment,
- fracture,
- dislocation,
- scoliosis,
- kyphosis,
- spinal tumor and
- failed previous fusion (pseudoarthrosis)

In addition, when used as a pedicle screw fixation system, the HydraLok System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft only having the device attached to the lumbar and sacral spine (L3 and below), who are having the device removed after the development of a solid fusion.

Prescription Use _____X_____ or Over-The-Counter Use

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051216