510(k) SUMMARY

K033961

APR 1 4 2004

SUBMITTED BY

Wendy Spielberger
Lead Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618
(949) 453-3200

December 18, 2003

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Appliance, Fixation, Spinal Interlaminal Orthosis
Common/Usual Name:	Spinal Interlaminal Orthosis Fixation
Product Classification:	Class II
Proprietary Name:	Altius OCT System

PREDICATE DEVICE

Predicate device information is included in this premarket notification.

INDICATIONS-FOR-USE

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Altius OCT System is indicated for:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Atlantoaxial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

The occipital bone screws are limited to occipital fixation only.

The Altius OCT System can be linked to the Synergy Spinal System using the Transitional Rods and Rod Connectors from the Altius OCT System.

DEVICE DESCRIPTION

The Altius OCT System is a titanium system composed of rods, bone screws, hooks, set screws, nuts, cross connectors, plates. For occipito-cervico-thoracic fusion, the occipital plate is fixed to the occiput with bone screws. The pre-bent rod is cut to the appropriate length. Bone screws are placed in the thoracic spine (T1-T3) and hooks are placed in the cervical spine. The rod is inserted and the construct is locked with screws and nuts. Cross connectors can be added to the construct.

COMPARISON TO THE PREDICATE DEVICE

Based on the same indications for use, intended use, similarity in materials of construction and equivalent biomechanical performance, the Altius OCT System is considered substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Wendy Spielberger
Lead Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K033961
Trade/Device Name: Altius OCT System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: March 18, 2004
Received: March 19, 2004

Dear Ms. Spielberger:

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.

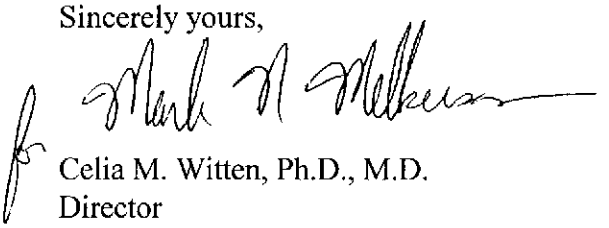
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033961

Device Name: Altius OCT System

Indications-For-Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Interpore Cross International Altius OCT System is indicated for:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondyloslisthesis
- Spinal stenosis
- Fracture/dislocation
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- Tumors

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The Altius OCT System can be linked to the Synergy Spinal System using the Transitional Rods and Rod Connectors from the Altius OCT System.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR _____ Over-The-Counter Use
(PER 21 CFR 801.109)

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

510(k) Number K033961

(Optional Format 1-2-96)