SEP 2 4 2004

Cervical Plate
510(k) Summary
August 24, 2004

K042317

Submitter	Scient'x Batiment Calypso Parc Ariane 3 78284 Guyancourt FRANCE
Contact person	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199
Trade Name	Cervical Plate
Common name	Anterior cervical plate
Classification name	Class II per 21 CFR section 888.3060
Product Code	KWQ
Equivalent Device	Scient'x Anterior Cervical Plate (K013439).

Device Description

The Cervical Plate system consists of multiple sized plates and screws. All components are fabricated from anodized titanium alloy (Ti-6Al-4V) that conforms to ASTM F136. Fixation is provided by inserting screws through holes in the plate into the vertebral bodies of the cervical spine.

The screws utilized in the Cervical Plate are of the self tapping cortical type and are available in Ø4.0mm and a variety of lengths.

Intended Use

The Cervical Plate is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during development of a solid fusion in patients with the following conditions:

- degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- spondylolisthesis,
- trauma (i.e., fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis, and
- failed previous fusion.

However, this device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine

Summary of Technological Characteristics Compared to Predicate Device

The Cervical Plate is similar in indications, material, design, geometry, screw locking mechanism, length, strength, and screw diameter, length and thread form.

Summary Nonclinical Tests

Testing was performed according to ASTM F1717.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2004

Scient'x
C/o Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, Texas 78681

Re: K042317
Trade/Device Name: Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 24, 2004
Received: August 26, 2004

Dear Mr. Webb:

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,

for Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known): K042317

Device Name: Cervical Plate

Indications for Use:

The Cervical Plate is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during development of a solid fusion in patients with the following conditions:

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- spondylolisthesis,
- trauma (i.e., fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis, and
- failed previous fusion.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K042317