MAY 31 2002

K021379 1/1

510(k) SUMMARY of Safety and Effectiveness

Sponsor:

OrthoTec, LLC
9595 Wilshire Blvd. Suite 502
Beverly Hills, CA 90212
Phone: (310) 557-2000 & (310) 273-1500
Fax: (310) 843-9500

Contact Person:

Patrick Bertranou, MD

Proprietary Trade Name:

SCS Claris Lengthened Lateral Connector (AL06)

Device Description:

The SCS Claris Spinal Lengthened Lateral Connectors are available in one size only and are used to connect the rods and screws of the SCS Claris Spinal System.

Intended Use:

When used as a nonpedicle posterior system, the SCS system is indicated for patients with: degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, failed previous fusion (pseudarthrosis).

When used as an anterolateral/anterior system the SCS system is indicated for patients with: degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, failed previous fusion (pseudarthrosis)

When used as a posterior pedicle system, the SCS system is indicated for use in skeletally mature patients L3 and below who are: having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, receiving fusions using autogenous bone graft only, having the device fixed or attached to the lumbar and sacral spine, having the device removed after the development of a solid fusion mass. Screw fixation is limited to L3 and below.

Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients 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 neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous fusion (pseudarthrosis).

Materials:

The SCS Claris Spinal System Lengthened Lateral Connector (AL06) is manufactured from stainless steel (ASTM F136 / ISO 5832-1) and titanium alloy (ASTM F138 / ISO 5832-3).

Substantial Equivalence:

Documentation was provided which demonstrated the SCS Claris Lengthened Lateral Connector (AL06) to be substantially equivalent to the previously cleared SCS Extremity Connector (AL02). The substantial equivalence is based upon equivalence in indications/intended use, manufacturing methods, interconnection (attachment) mechanism, basic design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2002

OrthoTec, LLC
c/o Ms. Karen Warden, MEBE
8202 Sherman Road
Cleveland, Ohio 44026-2141

Re: K021379
Trade Name: SCS Claris Spinal System Lengthened Lateral Connector (AL06)
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050 and 21 CFR 888.3060
Regulatory Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis and Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP, KWQ
Dated: April 26, 2002
Received: May 1, 2002

Dear Ms. Warden:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K021379

Device Name: ***SCS Claris Spinal System***

Indications for Use:

When used as a nonpedicle posterior system, the SCS system is indicated for patients with:

degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
spondylolisthesis
fracture
spinal stenosis
deformities (i.e., scoliosis, kyphosis, lordosis)
tumors
failed previous fusion (pseudarthrosis)

When used as an anterolateral/anterior system the SCS system is indicated for patients with:

degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
spondylolisthesis
fracture
spinal stenosis
deformities (i.e., scoliosis, kyphosis, lordosis)
tumors
failed previous fusion (pseudarthrosis)

When used as a posterior pedicle system, the SCS system is indicated for use in skeletally mature patients who are:

having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint
receiving fusions using autogenous bone graft only
having the device fixed or attached to the lumbar and sacral spine
having the device removed after the development of a solid fusion mass.
screw fixation is limited to L3 and below.

Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients 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 neurologic impairment
fracture
dislocation
scoliosis
kyphosis
spinal tumor
failed previous fusion (pseudarthrosis)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use_____

for Mark N Milhoan

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

510(k) Number K021379