510(k) Summary

K033951
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Date
December 19, 2003

Submitter
Pisharodi Surgicals, Inc.
942 Wildrose Lane
Brownsville, TX 78520

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

JUL 0 1 2004

Common name
Anterior vertebral body fixation system

Classification name
Spinal Intervertebral Body Fixation Orthosis per 21 CFR section 888.3060.

Equivalent Device
The Radix Cervical Plate is equivalent in design, material and indications as the Synthes Anterior CLSP System (K030866) and EBI VueLock Cervical Plate (K010003).

Device Description
The Radix Cervical Plate is a one or two level plate that is secured to the anterior cervical vertebral bodies with uni-cortical bone screws. The plate is available in twelve lengths ranging from 38mm to 60mm in length. It has six holes to receive the bone screws. The screw holes allow variable angulation of the screws.

Ease of intra-operative handling is enhanced by pre-contouring the plates in two directions to facilitate adaptation to the patient's anatomy and self-tapping uni-cortical screws, which shorten operating time. The screws are Ø3.9mm and are available in five lengths, 10mm to 18mm. The self-tapping thread of the screws eliminates the need for preliminary tapping.

Intended Use
Radix Cervical Plate is intended for anterior screw fixation of the cervical spine.

Indications for use include:
- degenerative disc disease (ddd) defined as back 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
- failed previous fusion

Warning:" This device is not approved 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 Radix Cervical Plate is similar in material, plate lengths, ability to angulate and lock the bone screws, pre-contoured plates and indications.

Summary Nonclinical Tests
Testing was performed according to ASTM 1717 with results comparable to other cervical plates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Pisharodi Surgicals, Inc.
C/o J.D. Webb
The Orthomedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K033951
Trade/Device Name: Radix Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 19, 2004
Received: April 22, 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) 594-4692. 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

for 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): K033951

Device Name: Radix Cervical Plate

Indications for Use:

Radix Cervical Plate
Indications for Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR

Over-the-Counter Use ____

(Optional format 1-2-96) ____

Miriam C. Provost
(Division Sign-off)
Division of General, Neurological
and Restorative Devices

510(k) Number K033951