REMEDY™ Cervical Plate System
510(K) SUMMARY

Submitter

ArchiMed Inc.
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(800) 991-4559

Date: April 7, 2010

Contact:
Barry Aiken
ArchiMed Inc
50 W 3rd Ave
Collegeville, PA 19426

Trade Name **REMEDY™ Cervical Plate System**

Common Name Cervical Plating Instrumentation

APR - 7 2010

Classification
KWQ – 888.3060
Class II, Spinal Intervertebral Body Orthosis

Device Description

The Remedy Cervical Plate System consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The REMEDY Cervical Plate System implant components are made from titanium alloy described by ASTM F136.

Indications for Use

The REMEDY Cervical Plate System is intended for anterior interbody screw/plate fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) Trauma (including fractures), 3) Tumors, 4) Deformity (defined as kyphosis, lordosis, or scoliosis), 5) Pseudarthrosis, and/or 6) Failed previous fusions.

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

Non-Clinical Tests

Static Axial Compression Bending, Dynamic Axial Compression Bending, and Static Torsion Tests per ASTM F1717 demonstrate the REMEDY Cervical Plate System is substantially equivalent to the predicate devices.

Predicate Devices

The REMEDY Cervical Plate System has identical indications for use, material, and employs the same principles of operation as predicate devices. Furthermore, its prominence on the spine, range of sizes, and screw angulation are at or within the limits of the predicate devices. Based on these factors, the REMEDY Cervical Plate System is Substantially Equivalent to the predicate devices.

Device	Company	510(k) Number
Atlantis Vision	Medtronic	K021461
Venture	Medtronic	K042922
Premeir	Medtronic	K992110
Zephir	Medtronic	K030327
Skyline	Depuy	K052552
Uniplate	Depuy	K042544
Swift	Depuy	K040655
Reflex Hybrid	Stryker Spine	K040261
Trinica Select	Zimmer	K022344
Providence	Globus	K070775
Vectra-T	Synthes Spine	K030866
CSLP	Synthes Spine	K000536
Pyrenees	K2M	K060442
Helix ACP	Nuvasive	K071329
Gradient Plus	Nuvasive	K053581

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

ArchiMed, Inc.
% Mr. Barry Aiken
Chief Financial Officer
50 West 3rd Avenue
Collegeville, Pennsylvania 19426

APR - 7 2010

Re: K100215
Trade/Device Name: REMEDY™ Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 19, 2010
Received: January 25, 2010

Dear Mr. Aiken:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K100215

Device Name: REMEDY™ Cervical Plate System

Indications for Use: The REMEDY™ Cervical Plate System is intended for anterior interbody screw/plate fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

1) Degenerative Disc Disease
(as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),

2) Trauma (including fractures),

3) Tumors,

4) Deformity (defined as kyphosis, lordosis, or scoliosis),

5) Pseudarthrosis, and/or

6) Failed previous fusions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100215