

MAY - 6 2004

510(k) Summary of Safety and Effectiveness

K040397
Page 1 of 1

- (1) **Submitter's name:** Encore Medical, L.P.
Submitter's address: 9800 Metric Blvd, Austin, TX 78758
Submitter's telephone number: (512) 834-6237
Contact person: Debbie De Los Santos
Date summary prepared: February 9, 2004

- (2) **Trade or proprietary device name:** Cyclone™ Anterior Cervical Plate System
Common or usual name: Anterior Cervical Plate
Classification name: 888.3060 -- Spinal Intervertebral Body Fixation Orthosis

- (3) **Predicate devices:** Cyclone™ Anterior Cervical Plate System

- (4) **Subject device description:**
The Cyclone™ Anterior Cervical Plate System is a unilateral fixation device consisting of cervical plates (locking mechanism is pre-assembled to plates) and unicortical screws made from titanium alloy in conformance with ASTM F136. The plates are offered in one-level, two-level, three-level, and four-level fusion configurations (14mm-88mm). There are four different lengths of the standard 4mm diameter screw (12, 14, 16, and 18mm). The rescue screw has a diameter of 4.4mm and lengths are 12, 14 and 16mm.

- (5) **Subject device intended use:**
The Cyclone™ Anterior Cervical Plate System is a unilateral fixation device intended to provide stabilization during the process of cervical spinal fusion (C2-C7) in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

- (6) **Basis for Substantial Equivalence:**
The Cyclone™ Anterior Cervical Plate System is similar in design, indications and materials to Cyclone™ Anterior Cervical Plate System (K031214).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2004

Ms. Debbie De Los Santos
Supervisor, Regulatory/Clinical Services
9800 Metric Boulevard
Austin, TX 78758

Re: K040397

Trade/Device Name: Cyclone™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 12, 2004
Received: February 17, 2004

Dear Ms. De Los Santos:

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.

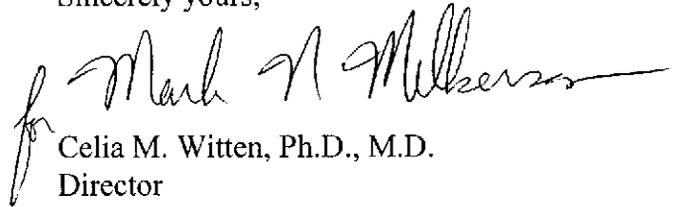
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Debbie De Los Santos

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” (21 CFR 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal stroke at the end.

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): K040397

Device Name: Cyclone™ Anterior Cervical Plate Line Extension

Indications For Use:

Cyclone™ Anterior Cervical Plate
Indications For Use

The Cyclone™ Anterior Cervical Plate is a unilateral fixation device intended to provide stabilization during the process of cervical spinal fusion (C2-C7) in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

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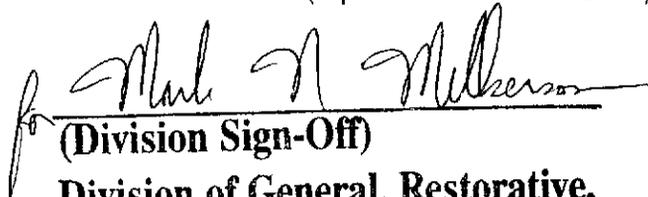
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)_


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K 04 0397