SEP 23 2003

K031214

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510(k) Summary of Safety and Effectiveness

(1)	**Submitter's name:**	Encore Medical, L.P.
	Submitter's address:	9800 Metric Blvd, Austin, TX 78758
	Submitter's telephone number:	(512) 834-6255
	Contact person:	Debbie De Los Santos
	Date summary prepared:	April 15, 2003
(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:**	Trinica Select Anterior Cervical Plate Zephir Anterior Cervical Plate

(4) **Subject device description:**

The Cyclone™ Anterior Cervical Plate System is a 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, and three-level fusion configurations (14mm-69mm). 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 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 Centerpulse Spine-Tech's Trinica Select Anterior Cervical Plate (K022344) and Medtronic Sofamor Danek's Zephir Anterior Cervical Plate (K994239).

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K031214

510(k) Number (if known): _____

Device Name: Cyclone™ Anterior Cervical Plate System

Indications For Use:

Cyclone™ Anterior Cervical Plate System
Indications For Use

The Cyclone™ Anterior Cervical Plate System is intended for anterior inter-body screw fixation to provide stabilization of cervical spinal fusion (C2-C7). This system is indicated for use 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

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

Re: K031214
Trade/Device Name: Cyclone™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 16, 2003
Received: July 10, 2003

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.

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 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): K031214

Device Name: Cyclone™ Anterior Cervical Plate System

Indications For Use:

Cyclone™ Anterior Cervical Plate System
Indications For Use

The Cyclone™ Anterior Cervical Plate System is 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____
(per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031214