K072463

3 510(k) Summary

Submitter Contact Information:

Satyrne Medical
1909 Gold Ave. SE #1
Albuquerque, NM 87106
(505) 620-3856

Contact Person: Scott T. Lovald
Summary prepared 8/24/2007

NOV 2 9 2007

Trade Name: InterFlex Mandibular Fixation System

Device Classification: Class II
Common Name: Bone Plates
Regulation Number: 21 CFR 872.4760
Classification Product Code: 76 JEY

Predicate Devices

Stryker Instruments -Universal CMF System (K022185)
Synthes – Mandibular Modular Fixation System (K954385)

Device Description

Satyrne InterFlex Mandibular Fixation System is a new bone plate system for use in oral and maxillofacial surgery. The design includes plates of different thicknesses that are secured to the mandibular bony tissue using bone screws of varying lengths and designs. The bone plates and bone screws will be manufactured of commercially pure (CP) titanium or Ti6Al4V alloy in compliance with ASTM F67 and ASTM F136.

Intended Use

Satyrne's InterFlex Mandibular Fixation System is intended for the stabilization and rigid fixation of fractures and reconstructive procedures of the mandibular skeleton. Each device is intended for single use only in conjunction with other titanium and titanium alloy implants.

Substantial Equivalence

Based on mechanical test results, the Satyrne InterFlex Mandibular Fixation System is substantially equivalent to the legally marketed Stryker Leibinger Universal CMF System

K022185 and the Synthes Mandibular Modular Fixation System K954385. The plates and screws are made of the same material as predicate devices. The system contains various shapes of plates and screws similar to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

Mr. Scott Lovald
CTO
Satyrne Medical
1909 Gold Avenue SE #1
Albuquerque, New Mexico 87106

Re: K072463
Trade/Device Name: InterFlex Mandibular Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 26, 2007
Received: August 31, 2007

Dear Mr. Lovald:

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.

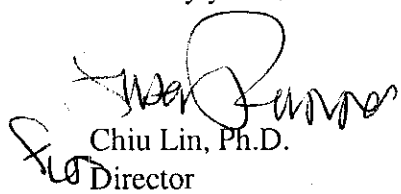
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 Indications for Use

510(k) Number (if known):

Device Name: InterFlex Mandibular Fixation System

Indications for Use:

Satyrne's InterFlex Mandibular Fixation System is intended for the stabilization and rigid fixation of fractures and reconstructive procedures of the mandibular skeleton. Each device is intended for single use only in conjunction with other titanium and titanium alloy implants.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072463