NOV 1 2 2003

K032520

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

APPLICANT: TEKKA
Parc Inopolis
Route de Vourles
69230 Saint Genis Laval
France
Tel #: 33.4.78.56.97.00
Fax #: 33.4.78.56.01.63

Contact Person: Benoit Rodriguez
Date Prepared: August 8, 2003

DEVICE TRADE NAME: ORTRAUTEK TRAUMA SYSTEM
COMMON OR USUAL NAME: Bone Plate System
CLASSIFICATION NAME: Bone Plate
DEVICE CLASSIFICATION: Class II, 21 CFR § 872.4760

PREDICATE DEVICE:
K854886: Wuerzburg Titanium Mini Bone Plate and Bone Screws.
K022185: Stryker Instruments - Universal CMF System.
K002619: Stryker Instruments – NewGen System
K974555: Synthes 2.0 mm Locking Plate System (2.0 LPS)
K944561: KLS-Martin Micro Osteosynthesis System (1.0 mm)
K953385: Lorenz 1.00 mm, 1.5 mm, 2.0 mm System

DEVICE DESCRIPTION:
The ORTRAUTEK TRAUMA SYSTEM is composed of bone plates and bone screws of various shapes and sizes, and associated accessories for use in oral and maxillofacial surgery. The accessories include the instruments used to implant bone plates and screws. These accessories include screwdrivers, forceps, and drills. The bone plates meet ASTM F67 standards of unalloyed titanium surgical implants. The bone screws meet ASTM F136 standards. The system contains various shapes and sizes of plates. The thickness of these plates is either 1.0 mm or 0.6 mm. The system contains bone screws that are 2.0 mm, 2.4 mm, or 1.5 mm.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The ORTRAUTEK TRAUMA SYSTEM is identical in material, design, composition, function, and intended use to predicate devices. The intended use is similar to K022185 and K002619. 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.

INTENDED USE:
The ORTRAUTEK TRAUMA SYSTEM is a cranio-maxillofacial titanium plate and screw system intended for osteotomy, stabilization and rigid fixation of cranio-maxillofacial fracture and reconstruction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

Tekka
C/O Mr. Fayyaz Memon
Alta Medical Incorporated
6512 Bannockburn Drive
Bethesda, Maryland 20817

Re: K032520
Trade/Device Name: Ortrautek Trauma System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 7, 2003
Received: August 16, 2003

Dear Mr. Memon:

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) 594-4613. 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,

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

K032520

Indication for Use Statement

Applicant: TEKKA, France

510(K) Number: (if known): K032520

Device Name: ORTRAUTEK TRAUMA SYSTEM

Indication for Use:

The ORTRAUTEK TRAUMA SYSTEM is a cranio-maxillofacial titanium plate and screw system intended for osteotomy, stabilization and rigid fixation of cranio-maxillofacial fracture and reconstruction.

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

510(k) Number: K032520

(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 _____