K073307

OCT 29 2008

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:

BIO-TECHNOLOGY USA, INC.
6175 NW 167th Street, Unit # G-8
Miami, Florida, 33015

Date Summary Prepared: October 10, 2008

Contact Persons:

Krista Oakes
Emergo Group, Inc.
1705 S. Capital of Texas Hwy., Suite 500
Austin, TX 78746

Telephone: 512-327-9997
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Device Name:

Trade Name(s): MaxFace Maxillofacial Ostheosynthesis System
Classification Name: Bone Plate
Classification Regulation: 21 CFR 872.4760
Panel: Dental
Product Code: JEY

Predicate Device Information:

This device is substantially equivalent to the KLS Martin Micro-Osteosynthesis System, marketed under K944565, and the Synthes Craniofacial Plates, marketed under K021642.

Device Description:

The MaxFace Maxillofacial Ostheosynthesis System is composed of plates and screws, which are available in four different kit sizes: Cranio, Micro, Standard, and Macro systems.

Intended Use: The MaxFace Maxillofacial Ostheosynthesis System is indicated for trauma fixation of the superior, middle and inferior segments of the facial skeleton, for ostheosynthesis of corrective osteotomies in congenital deformities treatment (acquired or in development) and for the fixation of grafts in reconstructive surgeries.

Contraindications include:

- Exposed plates and screws
- Fixations on the dental area
- Local infection

Comparison to Predicate Device:
This device is equivalent to the predicate device in intended use and physical characteristics.

Testing and Conclusions:
Bench performance testing demonstrates substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bio-Technology USA, Incorporated
C/o Ms. Krista Oakes
Senior Consultant
Emergo Group, Incorporated
1705 South Capital of Texas Hightway,
Suite 500
Austin, Texas 78746

OCT 29 2008

Re: K073307
Trade/Device Name: MaxFace Craniomaxillofacial Osteosynthesis System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: October 13, 2008
Received: October 16, 2008

Dear Ms. Oakes:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K073307

Device Name: MaxFace Craniomaxillofacial Osteosynthesis System

Indications for Use: The MaxFace Maxillofacial Ostheosynthesis System is indicated for trauma fixation of the superior, middle and inferior segments of the facial skeleton, for ostheosynthesis of corrective osteotomies in congenital deformities treatment (acquired or in development) and for the fixation of grafts in reconstructive surgeries.

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

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