K051236

510(K) SUMMARY

AUG 2 2 2005

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746
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Contact Person:	Jennifer Damato Director RA/QA
Date of Summary:	10 May 2005
Device Name:	RESORB-X® SF
Trade Name:	RESORB-X® SF
Common Name:	Bone Plate
Classification Name and Number:	Bone Plate (872.4760)
Regulatory Class:	II
Predicate Devices:	RESORB-X® Resorbable Plating System (K011590) Siroson L and Sirosonic Ultrasonic Scalers (K033640) EMS Piezon® Master 600 (K022328)
Intended Use:	The RESORB-X® SF is intended for fractures of the craniofacial skeleton including, but not limited to, comminuted fractures of the naso-ethomoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, and midface fractures; and reconstructive procedures of the midface or craniofacial skeleton. The RESORB-X® SF pins are designed only to be inserted with the RESORB-X® SF Sonotrode device. The RESORB-X® SF is NOT intended for use in the mandible or full load-bearing situations, nor in areas of active infection or for patients with conditions including blood supply limitations, insufficient quantity or quality of bone, or latent infections. The RESORB-X® SF Sonotrode is NOT intended for any other use and is only intended for use for insertion of the RESORB-X® SF pins.

Device Description:

The RESORB-X® SF consists of RESORB-X® Pins made of Poly (D, L) - Lactide-Acid (PDLLA) of various diameters and lengths that are implanted utilizing ultrasonic force generated by an ultrasonic unit that causes a phase transition in the pin, allowing the pin to adapt to the previously drilled pilot hole in the surgical site and utilize the micro undercuts of the bone for retention. The RESORB-X® SF pins are designed to be used in conjunction with the previously cleared RESORB-X® Resorbable Plating System plates (K011590).

Technological Characteristics:

Similarities to Predicate

The RESORB-X® SF is identical to RESORB-X® Resorbable Plating System (K011590) in intended use and in chemical composition.

The RESORB-X® SF pin diameters and pin lengths are identical in diameter and length to RESORB-X® Resorbable Plating System (K011590)

The RESORB-X® SF ultrasound unit is similar to the Siroson L and Sirosonic Ultrasonic Scalers (K033640) and the EMS Piezon® Master 600 (K022328) in operating voltages, energy delivered and tip operating frequency.

Differences to Predicate

The RESORB-X® SF pins utilize a dual diameter stepped drill with a stop and does not require the hole to be pre-tapped. The RESORB-X® Resorbable Plating System (K011590) utilizes a single diameter drill and requires the hole to be tapped.

The RESORB-X® SF ultrasound unit produces an ultrasonic force to generate a phase transition in the pin which allows the pin to adapt to the previously drilled pilot hole in the surgical site and utilize the micro undercuts of the bone for retention. The Siroson L and Sirosonic Ultrasonic Scalers (K033640) and the EMS Piezon® Master 600 (K022328) generate an ultrasonic force for dental procedures.

Substantial Equivalence:

The RESORB-X® SF is substantially equivalent in intended use to the RESORB-X® Resorbable Plating System (K011590).

Discussion:

The RESORB-X® SF and the RESORB-X® Resorbable Plating System (K011590) screws are intended for identical surgical procedures. Further, the RESORB-X® SF is used in combination with the exact same RESORB-X® Resorbable Plating System (K011590) plates for fixation.

Mechanical tests have been preformed to compare the strength of the RESORB-X® SF pins with the RESORB-X® screws and the data is included in section F-3. To summarize the findings, the RESORB-X® SF pins have more favorable results (higher strength) than the previously cleared RESORB-X® screws.

The major difference between this product and the previously cleared product is in the method of insertion. Instead of using a drill, tap, screw method of insertion, the RESORB-X® SF uses the characteristics inherent in polymers allowing the polymer to mold into the surrounding space when heated. The heat, in this case, is generated by the fiction between the pin and the surrounding pilot hole though the use of an ultrasonic generator. The "phase" change that allows the pin to mold to the surgical site is temporary and is reversed when the ultrasonic force is removed. The heat that is transferred to the surrounding bone is not significant and is shown in section F-3.

Finally, the frictional heat that is necessary to allow the RESORB-X® SF pins to mold into the pilot hole is well below the temperatures used in manufacturing the product and the previously cleared the RESORB-X® Resorbable Plating System (K011590) screws. The limited duration and low temperature exposure used during insertion does not affect the molecular weight, the resorption or the strength retention of the product as shown in section F-3 and does not adversely affect the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

Ms. Jennifer Damato
Director RA/QA
KLS-Martin, L.P.
11239 St. Johns Industrial
Parkway South
Jacksonville, Florida 32246

Re: K051236
Trade/Device Name: RESORB-X® SF
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: July 22, 2005
Received: July 28, 2005

Dear Ms. Damato:

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

Indications for Use

510(k) Number (if known): K051236

Device Name: RESORB-X® SF

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Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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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