KLS martin L.P.
P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartin.com

K121606

**510(k) Summary**
**Section 21 CFR 807.92**

JAN 17 2013

| | |
|---|---|
| **Submitter:** | KLS Martin, L.P.<br>11201 Saint Johns Industrial Pkwy S<br>Jacksonville, FL 32246 |
| **Contact Person:** | Jennifer Damato<br>Director of Quality Mgt and Regulatory Affairs<br>Phone: 800-625-1557<br>Fax: 904-641-7378 |
| **Date Prepared:** | December 31, 2012 |
| **Trade Name:** | Resorb-X G |
| **Common Name:** | Resorbable Fixation System |
| **Classification:** | Preformed alterable cranioplasty plate<br>Class II, 21 CFR 882.5320, Product Code GWO<br><br>Cranioplasty plate fastener<br>Class II, 21 CFR 882.5360, Product Code HBW |
| **Predicate Devices:** | OSTEOTRANS™-MX **(K073006)**<br>Resorb-X G **(K112064)**<br>Synthes Rapid Resorbable Fixation System **(K062789)**<br>LactoSorb Trauma Plating System **(K992355)**<br>SonicWeld RX (Resorb-X) **(K080862)** |

**Device Description:**
The Resorb-X G product line consists of plates, meshes and pins manufactured in a variety of sizes and configurations to provide fixation and aid in the alignment and stabilization of fractures in reconstructive procedures. Resorb-X G is implanted using 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 plate, mesh and pin sizes and configurations are identical to components previously cleared in K080862, SonicWeld RX (Resorb-X). The PLLA/PGA material is identical to that cleared in K112064, Resorb-X G. This premarket notification is being submitted to expand the indications for use for Resorb-X G to include cranial use in pediatric and adult populations and includes additional sizes and configurations in the PLLA/PGA material for cranial use.

KLS martin L.P.

P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartin.com

## Technological Characteristics/Substantial Equivalence:

Device Comparison Table

| | **Resorb-X G** (Subject Device) | **OSTEOTRANS-MX Bioabsorbable Bone Fixation System** (K073006) | **Synthes (USA) Rapid Resorbable Fixation System** (K062789) | **Lactosorb Trauma Plating System** (K992355) | **Resorb-X G** (K112064) | **SonicWeld RX (Resorb-X)** (K080862) |
|---|---|---|---|---|---|---|
| **Indications for Use** | Resorb-X G is intended for use in non-load bearing fracture repair and reconstructive procedures in pediatric and adult populations. In addition, resorbable meshes, plates and pins may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in cranial reconstruction. | The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is intended for use in trauma and reconstructive procedures of the craniofacial skeleton, including fracture of the cranium, infant craniofacial surgery (i.e. cranioynostosis, congenital malformations), pediatric reconstructive procedures, reconstructive procedures of the cranium, craniotomy flap fixation. | The Synthes (USA) Rapid Resorbable Fixation System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, sheets, screws and tacks may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts, (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas. | A. General Indication: trauma procedures of the midface or craniofacial skeleton.<br>Specific Indications:<br>1. comminuted fractures of the naso-ethmoidal and intraorbital area.<br>2. comminuted fractures of the frontal sinus wall.<br>3. pediatric midface or craniofacial trauma.<br>4. LeFort (I, II, III) fractures.<br>5. orbital floor fractures.<br>6. fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones.<br>7. trauma of the craniofacial skeleton, including frontal, parietal, temporal, sphenoid, and occipital bones.<br>B. General Indications: reconstructive procedures of the midface or craniofacial skeleton.<br>Specific Indications:<br>1. infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)<br>2. LeFort (I, II, III) osteotomies.<br>3. tumor reconstruction in midface or craniofacial procedures.<br>4. bone graft procedures in the midface or craniofacial skeleton.<br>5. pediatric reconstructive procedures.<br>6. reconstructive procedures of the craniofacial skeleton including, frontal, parietal, temporal, sphenoid, and occipital bones.<br>7. craniotomy flap fixation. | The KLS Martin Resorb-X G is intended for use in non-load bearing fracture repair and reconstructive procedures in adolescent and adult populations. In addition, resorbable meshes, plates and pins may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in oral and maxillofacial reconstruction. | The KLS Martin SonicWeld RX (Resorb-X) is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, plates and pins may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in oral and maxillofacial reconstruction.<br><br>The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation. The KLS Martin SonicWeld RX (Resorb-X) is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.<br><br>The SonicWeld Rx pins are designed only to be inserted with the SonicWeld Rx Sonotrode device. |

KLS martin L.P.

P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartin.com

Device Comparison Table (Continued)

| | **Resorb-X G** (Subject Device) | **OSTEOTRANS-MX Bioabsorbable Bone Fixation System** (K073006) | **Synthes (USA) Rapid Resorbable Fixation System** (K062789) | **Lactosorb Trauma Plating System** (K992355) | **Resorb-X G** (K112064) | **SonicWeld RX (Resorb-X)** (K080862) |
|---|---|---|---|---|---|---|
| **Contraindications** | • High-load regions in the absence of traditional rigid fixation<br>• Active or latent infections<br>• Patients in a bad general state of health or suffering from metabolic disorders (such as diabetes) | • Insufficient quality and quantity of bone for attachment of graft.<br>• Blood supply limitation and/or previous infections, which could retard healing.<br>• Patients with active infection.<br>• Conditions, which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing and rehabilitation period. | These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. The Synthes Rapid Resorbable System is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine. | • Active infection.<br>• Patient conditions including, blood supply limitations, insufficient quantity or quality of bone stock or latent infection.<br>• DO NOT USE in full load bearing procedures.<br>• DO NOT USE in the temporomandibular joint (TMJ). | • High-load regions in the absence of traditional rigid fixation<br>• Active or latent infections<br>• Patients in a bad general state of health or suffering from metabolic disorders (such as diabetes) | The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation. The KLS Martin SonicWeld RX (Resorb-X) is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine. |
| **Target Population** | Adults & Pediatrics | Adults & Pediatrics | Adults & Pediatrics | Adults & Pediatrics | Adults & Adolecents | Adults & Pediatrics |
| **Anatomical Sites** | Cranial | Craniofacial | Craniofacial | Craniofacial | Oral & Maxillofacial | Craniofacial |
| **Standards Met** | ISO 10993-1,-5,-12,-18 ISO 11137-2, 11737-1,-2 | Unknown | Unknown | Unknown | Same as current submission | Same as current submission |
| **Materials** | 85% PLLA, 15% PGA | 30-40% u-HA, PLLA | 85% PLLA, 15% PGA | 82% PLLA, 18% PGA | 85% PLLA, 15% PGA | PDLLA |
| **Biocompatibility** | Tested to ISO 10993-1, -5, -12, -18 | Unknown | Unknown | Unknown | Tested to ISO 10993-1, -5, -12, -18 | ISO 10993 |
| **Sterility** | Provided Sterile (Gamma Radiation) | Provided sterile | Provided Sterile | Provided Sterile (ETO) | Provided Sterile (Gamma Radiation) | Provided Sterile (Gamma Radiation) |
| **Where used (hospital, home, etc)** | Health Care Facilities/ Hospitals | Health Care Facilities/ Hospitals | Health Care Facilities/ Hospitals | Health Care Facilities/ Hospitals | Health Care Facilities/ Hospitals | Health Care Facilities/ Hospitals |
| **Chemical Safety** | Tested to ISO 10993-12, -18 | Unknown | Unknown | Unknown | Tested to ISO 10993-12, -18 | ISO 10993 |
| **Breakdown Products** | $H_2O$ and $CO_2$ | $H_2O$, $CO_2$, Ca, $PO_4$ | $H_2O$ and $CO_2$ | $H_2O$ and $CO_2$ | $H_2O$ and $CO_2$ | $H_2O$ and $CO_2$ |
| **Resorption Time** | 12 - 14 months | 4 - 6 years | 12 months | 12 months | 12 - 14 months | 12-18 months |
| **Dimensions** | | | | | | |
| **Plate/Mesh Thickness** | 0.3 - 1.0 mm | 0.7 - 1.4 mm | 0.25 - 1.2 mm | 0.25 - 1.14 mm | 0.6 - 1.0 mm | 0.1 - 2.0 mm |
| **Max Mesh Dimensions** | 126 x 126 x 1.0 mm | 50 x 50 x 1.0 mm | 150 x 150 x 0.8 mm | 100 x 100 x 0.5 mm | 126 x 126 x 1.0 mm | 126 x 126 x 1.0 mm |

KLS martin L.P.
P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartin.com

Similarities to Predicates
Resorb-X G has the same intended use and fundamental technology as the predicate devices. Resorb-X G is identical in design to the components included in K080862 and identical in material to the Resorb-X G components cleared in K112064 and to the Synthes Rapid Resorbable Fixation System.

Differences to Predicates
Resorb-X G utilizes the previously cleared SonicWelder RX (K080862) for pin fixation. The OSTEOTRANS-MX System, Synthes Rapid Resorbable Fixation System, and LactoSorb Trauma Plating System utilize screw-type fixation.

**Performance Testing:**
Chemical analysis to ISO 10993-18 and cytotoxicity tests to ISO 10993-5 showed conformance to the standards tested. Mechanical degradation comparison testing between Resorb-X G and Resorb X (K080862) was performed on gamma-sterilized material over a period of 22 weeks. Results show higher tensile strength for Resorb-X G for the first 12 weeks, during which time bone consolidation would occur. A higher tensile strength for Resorb-X was observed in the following weeks, as the resorption rate for PDLLA is lower than that for PLLA-PGA. The results for Resorb-X G show 97% strength retention after 4 weeks, 80% after 8 weeks, and 15% strength retention at the conclusion of the test. Higher viscosity for Resorb-X G was also observed during the first 11 weeks while higher viscosity for Resorb-X was observed for the last 11 weeks. The profile for both polymers remained relatively constant for the duration of the test.

**Conclusion:**
Performance testing results and similarities in technological characteristics demonstrate that Resorb-X G is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2013

KLS Martin L.P.
% Ms. Jennifer Damato
Director of Quality Management & Regulatory Affairs
11201 Saint Johns Industrial Pkway S
Jacksonville, FL 32246

Re: K121606
Trade/Device Name: Resorb-X G
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, HBW
Dated: December 26, 2012
Received: January 4, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K121606

Device Name: Resorb-X G

Indications For Use:

Resorb-X G is intended for use in non-load bearing fracture repair and reconstructive procedures in pediatric and adult populations. In addition, resorbable meshes, plates and pins may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in cranial reconstruction.

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)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K121606