DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 27, 2015

Depuy Synthes Biomaterials
Jeffrey L. Dow, JD
Senior Principal Regulatory Affairs Strategy Advisor
1230 Wilson Drive
West Chester, Pennsylvania 19380

Re: K141385
Trade/Device Name: Depuy Synthes RAPIDSORB Injectable Polymer System (IPS)
Regulation Number: 21 CFR 882.5360
Regulation Name: Cranioplasty Plate Fastener
Regulatory Class: Class II
Product Code: HBW
Dated: February 23, 2015
Received: February 26, 2015

Dear Mr. Dow,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141385

Device Name
RAPIDSORB Injectable Polymer System (IPS)

Indications for Use *(Describe)*
The RAPIDSORB Injectable Polymer System (IPS) is intended for use in non-load bearing fracture repair and reconstructive procedures of the craniofacial skeleton (excluding the upper and lower jaw) in pediatric and adult populations. RAPIDSORB IPS fasteners are designed to be used for the fixation of RAPIDSORB plates, meshes, and sheets.

In addition, RAPIDSORB IPS implants and instruments may be used with RAPIDSORB meshes and sheets 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 craniofacial reconstruction (excluding the upper and lower jaw).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary **K141385**

Submitter:	DePuy Synthes Biomaterials 1230 Wilson Drive West Chester, PA 19380
Date of creation:	February 23, 2015
Company Contact:	Jeffrey L. Dow, JD Senior Principal R/A Strategy Advisor DePuy Synthes Biomaterials 484 467 4174 Fax: 484 356 9636 dow.jeff@synthes.com
Name of Device:	DePuy Synthes RAPIDSORB® Injectable Polymer System (IPS)
Device Classification:	Class II, 21 CFR § 882.5360
Product Code:	HBW
Common Name:	Cranioplasty Plate Fastener
Predicate Devices: (Please see **Table 1**, below**)**	Synthes (USA) Rapid Resorbable Tack System (K050204) Synthes (USA) Rapid Resorbable Fixation System (K062789) *(Principal Predicate)* KLS-Martin, L.P., SonicWeld RX (Resorb-X) (K080862) Biomet Inc., Lactosorb Trauma Plating System (K992355)
Indications for Use:	The RAPIDSORB Injectable Polymer System (IPS) is indicated for use in non-load bearing fracture repair and reconstructive procedures of the craniofacial skeleton (excluding the upper and lower jaw) in pediatric and adult populations. RAPIDSORB IPS fasteners are designed to be used for the fixation of RAPIDSORB plates, meshes, and sheets. In addition, RAPIDSORB IPS implants and instruments may be used with RAPIDSORB meshes and sheets 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 craniofacial reconstruction (excluding the upper and lower jaw)."

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TABLE 1: COMPARISON OF INDICATIONS AND TECHNOLOGIES BETWEEN IPS AND PREDICATES

DePuy Synthes RAPIDSORB® Injectable Polymer System (IPS) (K141385)	**Synthes (USA) Rapid Resorbable Tack System (K050204)**	**Synthes (USA) Rapid Resorbable Fixation System (K062789)**	***(Principal Predicate)* KLS-Martin, LP., SonicWeldRX (Resorb X) (K080862)**	**Biomet Inc., Lactosorb Trauma Plating System (K992355)**
Indications. DePuy Synthes RAPIDSORB Injectable Polymer System (IPS) is intended for use in non-load bearing fracture repair and reconstructive procedures of the craniofacial skeleton (excluding the upper and lower jaw) in pediatric and adult populations. RAPIDSORB IPS fasteners are designed to be used for the fixation of DePuy Synthes RAPIDSORB plates, meshes, and sheets. In addition, RAPIDSORB IPS implants and instruments may be used with RAPIDSORB meshes and sheets 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 craniofacial reconstruction (excluding the upper and lower jaw).	**Indication.** Synthes Rapid Resorbable Tack System is intended for use in fracture repair and reconstructions of the craniofacial skeleton. In addition, Rapid Resorbable Tacks may be used in non-load bearing applications for maintaining the relative position and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.	**Indication.** The Synthes (USA) Rapid Resorbable Fixation System is intended for use in fracture repair in 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 and/or containing, bony fragments, bone grafts, (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.	**Indication**.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, screws 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 reconstruction of the craniofacial or mandibular areas.	**Indication:** trauma procedures of the midface or craniofacial skeleton Specific Indications: 1. Comminuted fractures of the naso-ethmoidal infraorbital areas 2. Comminuted fractures of the frontal sinus wall 3. Pediatric midface or craniofacial trauma 4. LeFort (I,II,III) fractures 5. Orbital floor fractures 6. Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal,ethmoid, and lacrimal bones 7. Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones General Indication: reconstructive procedures of the midface or craniofacial skeleton Specific Indications: 1. Infant craniofacial surgery (i.e.craniosynostosis, congenital malformation, trauma, etc.) 2. LeFort (I,II,III) osteotomies 3. Tumor reconstruction in midsface or craniofacial procedures 4. Bone graft procedures in the midface or craniofacial skeleton 5. Pediatric reconstructive procedures 6. Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones 7. Craniotomy flap fixation
Procode: HBW, 882.5360	Procode JEY 872.4760	Procode JEY 872.4760	Procode JEY 872.4760	Procode HRS, HWC 888.3030
Material: 85:15 Poly (L-lactide co-glycolyde)	Material: 85:15 Poly (L-lactide co-glycolyde)	Material: 85:15 Poly (L-lactide co-glycolyde)	Material: Poly (D, L)-Lactide-Acid	Material: 82 poly L-lactide acid and 18% poly glycolic acid
Biocompatibility: Established	Biocompatibility: Established	Biocompatibility: Established	Biocompatibility: Established	Biocompatibility: Established
Resorption time: Approximately 12 months	Resorption time: Approximately 12 months	Resorption time: Approximately 12 months	Resorption time: unknown	Resorbtion time: Approximately 12 months
Sterile components: Single use only; Gamma or EtO sterilized	Sterile components: Single use only; Gamma or EtO sterilized	Sterile components: Single use only; Gamma or EtO sterilized	Sterile components: Single use only; Gamma or EtO sterilized	Sterile components: Single use only; Gamma or EtO sterilized
Radiolucent	Radiolucent	Radiolucent	Radiolucent	Radiolucent

Device Description: DePuy Synthes RAPIDSORB IPS Injectable Polymer System consists of a sterile resorbable polymer, 85:15 Poly (L-lactide co-glycolide) and a battery powered delivery device. The polymer can be extruded from the delivery device into a predrilled pilot hole at the surgical site.

The polymer is presented as a rod in a sterile package (cartridge) that fits into the delivery device. The device then briefly heats the polymer at the implant site beyond the glass transition temperature of the polymer, allowing the polymer to be extruded in a controlled manner in a preselected length from the device through a plate, mesh, or sheet and into a predrilled hole at the site of the defect. The extruded polymer fills the predrilled hole. Retention is attained through friction and interdigitation with the surrounding bone.

The delivery device consists of three principal components: 1) a Power Drive Unit, which is nonsterile and reusable, and which fits into and is enclosed by 2) a disposable, sterile, single-use, rigid plastic shell and cap, and 3) a sterile, single-use, battery pack that attaches to the shell and serves as the power source. The delivery device is comfortably shaped and balanced to fit the left or right hand of the surgeon.

Enclosing the Power Drive Unit thus assures sterile delivery of the polymer at the implant site. The brevity of the increase in the temperature of the polymer combined with the controlled, minimized volume of polymer implanted prevents tissue injury or necrosis at the implant site.

Nonclinical Tests (Please see **Tables 2 And 3** Below)

Biocompatibility testing of the IPS polymer implant and delivery device was performed in accordance with the applicable FDA guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" July 28, 2014, and applicable International Standards Organization requirements of ISO 10993 for implants of greater than 30 days duration, as well as those standards for brief patient contact. The results of all those tests showed that the IPS polymer implant and delivery device are biocompatible.[1]

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act 21 USC §301 *et seq.*, as amended, and as applied under 21 CFR Part 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalence under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein may be construed as an admission against interest under the US patent laws or their application by the courts.

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TABLE 2: NONCLINICAL TESTS SUMMARY,

Title	Test Article	Methods	Conclusion
ISO Guinea Pig Maximization Sensitization Test	RAPIDSORB IPS Delivery Device Shell, Battery Shell	Guinea pigs were injected with test article extract and FCA, and the same number guinea pigs were injected with control blank and FCA. Test animals were topically patched with test extract and control animals were patched with control blank. Patches were removed after 48 hours. After 2 weeks, the animals were patched with test extract and control blank. This test was conducted in accordance to ISO 10993-10:2010 part 10: Test for irritation and skin sensitization.	Pass.
IEC 60601-1 (ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012)	Accredited laboratory tests of compliance with the medical device electrical standards of IEC 60601including software of the Power Drive unit, shell, cap and battery	Such tests as are required for certification under ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012	Pass.
Controlled Extraction Study	85: 15 poly (L-lactide- co-glycolide)	The polymer cleared in K030069, K050204, and K062789 was compared to the polymer described in the IPS submission to establish its identity to the cleared polymer. This test followed test guidelines described in ISO 10993-18:2005.	The polymer in the IPS submission was found to be identical to the cleared polymers.
ISO Intra-cutaneous Reactivity Test	RAPIDSORB IPS Delivery Device Shell, Battery Shell	Test article was extracted at a ratio of 4 g to 20 mL in normal saline and sesame oil for 72 hours at 50^{o}C. Test articles and vehicle controls were injected into three male NZW rabbits. Rabbits were observed at 24, 48, and 72 hours. This test was performed in accordance with ISO 10993-10:2010	Pass. There were no significant dermal reactions observed.
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	RAPIDSORB IPS Delivery Device Shell, Battery Shell	The test article was extracted in E-MEM + 5% FBS for 24 hours at 37ºC. The L-929 cells were incubated with the extract for 72 hours. The cultures were evaluated for cytotoxic effects by microscopic examination at 24, 48, and 72 hours. . This test was performed in accordance with ISO 10993-5:2009	Pass. The test article did not induce cytotoxicity.
ISO Acute systemic Injection Test	RAPIDSORB IPS Delivery Device Shell, Battery Shell	Mice were treated by intravenous or intraperitoneal injection to screen for potential toxic effects as a result of a single-dose systemic injection as recommended in ISO 10993-11:2006.	Pass.

TABLE 3: IN VITRO AND ANIMAL TESTS DEMONSTRATING SUBSTANTIAL EQUIVALENCE,

Test	Test Method Summary	Results
Axial Pullout Test	The object of this in vitro bench test was to determine the pullout strength of 2 different IPS fasteners lengths compared to the predicate, a 1.5 x 3mm (length) Direct Drive Lactosorb Screw. Measurements were made at time points as the test materials degraded.	At each time point, the pull out strength, measured in Newtons, was significantly greater for the Rapidsorb IPS Fastener compared to the predicate Lactosorb.
Shear Testing	The object of this in vitro bench test was to compare the initial and degraded strength of the IPS fastener to that of the predicate Lactosorb Fastener at comparable time points.	Based on statistical comparison of data, the mean peak load of the Rapidsorb IPS fastener was superior to the mean peak load for the Lactosorb fastener.
Immature ovine model animal test	An animal test in an immature ovine model was undertaken to show the thermal effects of the IPS fastener compared to that of the KLS Sonic Weld Sonic Pin.	Evaluation of bone and soft tissues (dura matter and brain) associated with cranial implant sites treated with Rapidsorb IPS fasteners and the predicate Sonic Weld Sonic Pin fasteners demonstrated comparable biocompatibility, irritancy scores, and healing.

Conclusion.

Performance testing of the RAPIDSORB IPS has demonstrated that the subject device is substantially equivalent to the predicate devices.