December 7, 2017

Synthes USA Products, LLC
Nicholas Fountoulakis
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K170818
Trade/Device Name: Craniomaxillofacial Distraction System (CMFD)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Non-alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PBJ
Dated: November 8, 2017
Received: November 9, 2017

Dear Mr. Fountoulakis:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170818

Device Name
Craniomaxillofacial Distraction System (CMFD)

Indications for Use *(Describe)*
The DePuy Synthes CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the cranium, where gradual bone distraction is required in adults and pediatric patients.

Cranium
The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary

Date Prepared: November 7, 2017

1.1.Submitter

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1.2.Device

Name of Device: Craniomaxillofacial Distraction System (CMFD)
Common or Usual Name(s): Cranial Distraction System
Classification Name(s): Preformed nonalterable cranioplasty plate
Regulatory Class: Class II - 882.5330
Product Code: PBJ
Review Panel: Neurology

1.3.Predicate Devices

Primary Predicate: Zurich Distraction System's Arnaud Distractor (K010139)
Additional Predicate: Synthes Craniomaxillofacial Distraction System (K060138)

1.4.Indications for Use

The DePuy Synthes CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the cranium, where gradual bone distraction is required in adults and pediatric patients.

Cranium

- The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults.

1.5.Device Description

DePuy Synthes Craniomaxillofacial (CMF) Distraction System is a modular distractor system intended for correction and reconstruction of the cranium in adults, adolescents, children, and infants. The distractor construct consists of the distractor body, footplates, extension arms, and bone screws, all of which are available in multiple configurations to meet patient and surgeon needs as detailed in the table below.

	Distractor Body	**Footplates**	**Extension Arms**	**Bone Screws**
Dimensions	10, 15, 20, 25, 30, 35, and 40 mm lengths	Cloverleaf and mesh designs Accept 1.5, 2.0, and 2.4 mm diameter screws	Rigid lengths are 20, 40, and 60 mm Flexible lengths are 30, 40, and 60 mm	1.5, 2.0, and 2.4 mm diameter 4 – 12 mm lengths
Materials	• TAN (ASTM F1295) • L605 (ASTM F90) • CoCrMo (ASTM F1537) • MP35N (ASTM F562)	• CP2 and CP4 Titanium (ASTM F67)	• TAN (ASTM F1295) • L605 (ASTM F90) • MP35N (ASTM F562) • Silicone (ASTM F2042)	• CP Titanium (ASTM F67) • TAN (ASTM F1295)

The distractor body is first secured to bone using footplates and screws, and then activation of the distractor is accomplished through the rotation of an advancement/lead screw with an activation instrument percutaneously.

1.6.Comparison to Predicate Devices

System/Device Name	Synthes Craniomaxillofacial Distraction System	KLS Zurich Distraction System's Arnaud Distractor	Synthes Craniomaxillofacial Distraction System (previous design)
Indications	The DePuy Synthes CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device. The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the cranium, where gradual bone distraction is required in adults and pediatric patients. DePuy Synthes CMF Distraction System is intended for single use only. Cranium • The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults.	The Zurich Distraction System includes devices intended as a bone stabilizer and lengthening (and/or transport) device when correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, symphysis), midface, and cranial bones require gradual distraction.	The Synthes Craniomaxillofacial Distraction System (CMF Distraction System) is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The Synthes CMF Distraction System is intended for single use only. The Synthes Pediatric CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required in children under the age of 12 months. The Synthes Pediatric CMF Distraction System is intended for single use only.
Contraindications	The Synthes CMF Distraction System is contraindicated for		Use of the Synthes CMF Distraction System is contraindicated in

System/Device Name	Synthes Craniomaxillofacial Distraction System	KLS Zurich Distraction System's Arnaud Distractor	Synthes Craniomaxillofacial Distraction System (previous design)
	patients sensitized to nickel, cobalt chromium, silicone or molybdenum.		patients previously sensitized to nickel
Where Used	Hospital, home	Hospital, home	Hospital, home
System Features	Modular design includes body, plates, and removable activation arms Surgeon and Patient Facing Instrumentation	Pre-assembled distractor body and plates with removable and non-removable activation arm Surgeon and Patient Facing Instrumentation	Modular design includes body, plates, and removable activation arms Surgeon and Patient Facing Instrumentation
Distractor Body Specifications	• End and center translating • 10 - 40 mm lengths • Accommodates left and right placement • Available with or without universal joint • Spring clip to prevent inadvertent reversing	• End and center translating • 20 mm and 30 mm lengths • Accommodates left and right placement • Available with or without universal joint (2.0 mm size)	• End and center translating • 10 - 40 mm lengths • Accommodates left and right placement • Available with or without universal joint
Plate Specifications	• Cloverleaf and mesh designs • Symmetric design • May be cut and bent • Fixed with 1.5, and 2.0 mm Screws	• Mesh design • Symmetric design • May be cut and bent • Fixed with 1.5, and 2.0 mm Screws	• Cloverleaf, mesh, and elevated mesh designs • Symmetric design • May be cut and bent • Fixed with 1.0, 1.3, 1.5, and 2.0 mm PlusDrive Screws

System/Device Name	Synthes Craniomaxillofacial Distraction System	KLS Zurich Distraction System's Arnaud Distractor	Synthes Craniomaxillofacial Distraction System (previous design)
	• Fixed with 2.0 and 2.4 mm Emergency Screws • Fixed with 2.0 mm Locking Screws	• Fixed with 1.8, and 2.3 mm Emergency Screws	• Fixed with 1.2, 1.7, 2.0, 2.4 mm PlusDrive Emergency Screws • Fixed with 2.0 mm Locking Screws
Extension Arm Specifications	• Point of activation moved away from distractor for patient access • Rigid and flexible options • May be removed without surgical procedure • Rigid lengths are 20, 40, and 60 mm • Flexible lengths are 30, 40, and 60 mm • May be combined to increase length	• Point of activation moved away from distractor for patient access • Rigid and flexible options (2.0 mm size) • May be removed without surgical procedure (2.0 mm size) • Rigid lengths are 25, 33, 35, 43, 45, 50, and 53 mm • Flexible lengths are 30, 33, 40, and 50 mm (2.0 mm size) • May be combined to increase length (2.0 mm size)	• Point of activation moved away from distractor for patient access • Rigid and flexible options • May be removed without surgical procedure • Rigid lengths are 20, 40, and 60 mm • Flexible lengths are 30, 40, and 60 mm • May be combined to increase length
Operating Principle(s)	Advancement/lead screw adjustment of metallic plate and screw construct to achieve distraction osteogenesis	Advancement/lead screw adjustment of metallic plate and screw construct to achieve distraction osteogenesis	Advancement/lead screw adjustment of metallic plate and screw construct to achieve distraction osteogenesis
Materials	**Distractor Bodies:** Titanium Alloy • TAN (ASTM F1295) Chromium Cobalt • L605 (ASTM F90) • CoCrMo (ASTM F1537) • MP35N (ASTM F562)	**Distractor Body:** Titanium Alloy • TAV (ASTM F136)	**Distractor Bodies:** Titanium Alloy • TAN (ASTM F1295) Chromium Cobalt • L605 (ASTM F90)

System/Device Name	Synthes Craniomaxillofacial Distraction System	KLS Zurich Distraction System's Arnaud Distractor	Synthes Craniomaxillofacial Distraction System (previous design)
	Plates: CP2 or CP4 Titanium (ASTM F67) **Extension Arms:** Titanium Alloy • TAN (ASTM F1295) Chromium Cobalt • L605 (ASTM F90) • MP35N (ASTM F562) Silicone (ASTM F2042) **Screws:** • TAN (ASTM F1295)	**Plates:** CP Titanium (ASTM F67) **Extension Arms:** Titanium Alloy • TAV (ASTM F136) **Screws:** • CP Titanium (ASTM F67)	**Plates:** CP2 or CP4 Titanium (ASTM F67) **Extension Arms:** Titanium Alloy • TAN (ASTM F1295) Chromium Cobalt • L605 (ASTM F90) • MP35N (ASTM F562) Silicone (ASTM F2042) **Screws:** • CP Titanium (ASTM F67) • TAN (ASTM F1295)
Sterility	Nonsterile Sterilized to SAL of 10^{-6} via steam (moist-heat) prior to use	Nonsterile Sterilized via steam (moist-heat) prior to use	Nonsterile Sterilized to SAL of 10^{-6} via steam (moist-heat) prior to use

1.6.1. Summary Comparison of Intended Use

Both the subject DePuy Synthes CMFD System and the KLS Zurich Distraction System's Arnaud Distractor (K010139) are indicated for correction of congenital deficiencies or post-traumatic defects of the cranium where gradual bone distraction is required. Additionally, clinical literature is provided in this submission discussing the effective use of the previous design of Synthes CMF Distraction System (K060138) in cranial distraction osteogenesis. The proposed use of the subject CMFD in the cranium does not constitute a new intended use not already addressed by the predicate device.

1.6.2. Summary Comparison of Technological Characteristics

The major technological differences between the subject CMFD in comparison to predicate KLS Zurich Distraction System's Arnaud Distractor (K010139) are:

- The subject device features a reversing prevention mechanism while the predicate does not. Non-clinical performance data of the reversing prevention mechanism demonstrates its efficacy.
- The subject device is made of commercially pure titanium, titanium alloy (TAN), cobalt chromium alloys (L605, MP25N, and CoCrMo), and silicone while the predicate is made of titanium and titanium alloy (TAV). However, these materials were used in other implantable components of the previous design of CMFD and are materials with established biocompatibility.

1.7.Non-clinical performance data

Non-clinical performance data demonstrates that the technological differences of the CMFD System do not raise new questions of safety and efficacy with respect to the predicate devices, and therefore support substantial equivalence:

Test Name	Test Method Summary	Results
Reversing Prevention	Anatomically simulated spinning and vibration of the subject distractor and the previous design of CMFD.	The subject device does not reverse unintentionally under the same conditions where the previous design of CMFD reversed.
Construct bending strength	Four-point bend test setup of a subject device construct in comparison to the predicate KLS Zurich Distraction System's Arnaud Distractor, and analysis comparing the subject design to the previous design of CMFD.	The CMFD construct is stronger than the predicate KLS Arnaud distractor, and the design changes relative to the previous design in K060138 do not affect the strength of the distractor construct.

Torque Input/Force Output and Construct Torsional Strength	This testing challenged the construct in torsion by applying an increasing torque (torque input) to the activation end of the device through an extension arm until failure of the device occurred.	The device is capable of outputting the force required to distract bone in the cranium without failing.
Extension arm interface tensile strength	This testing challenged the interface between the distractor and extension arm to ensure the interface can withstand a tensile force based on a human factors benchmark.	The redesigned CMFD meets the same human factors benchmark as the previous design of CMFD.
Biocompatibility	All subject devices with the exception of the modified distractor bodies utilize the same materials and manufacturing processes as the predicate devices cleared in K060138, and therefore biocompatibility testing was not provided. For the modified distractor bodies, a risk based assessment per ISO 10993-1 was conducted, and supporting biocompatibility testing was provided.	The results of biocompatibility risk assessment and testing demonstrate that the material change to the distractor body does not raise new questions of safety or efficacy with respect to biocompatibility.
Steam Sterilization Validation	The sterilization parameters were validated using the "overkill" method as referenced in Annex D of ANSI/AAMI/ISO 17665-1 in order to assure a Sterility Assurance Level (SAL) of 10^{-6}.	The devices may be effectively steam sterilized by the proposed parameters, which are the same parameters as the previous design of CMFD.
Endotoxin Testing	Endotoxin levels for finished subject devices were quantified using a Kinetic Turbidimetric method.	The subject devices meet the maximum endotoxin testing limit of 2.15 EU/device.

1.8.Clinical performance data

Clinical literature discussing the application of the previous design of CMFD (K060138) in the cranium is provided in this submission. A literature review was conducted and seven articles were identified discussing the use of the previous design of CMFD (K060138) in the cranium. The previous design of CMFD (K060138) was identified through narrative descriptions, x-rays, and/or images within the articles.

1.9.Substantial Equivalence

Results of non-clinical performance testing, discussions of clinical literature, and comparison to predicate devices included in this submission demonstrate that:

- Technological differences of the CMFD System in comparison to the predicate devices does not raise new questions of safety and efficacy
- The proposed CMFD System has the same intended use as the predicate devices

It is concluded that the information provided in this submission supports substantial equivalence.