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

May 8, 2017

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

Re: K162594
Trade/Device Name: Craniomaxillofacial Distraction System (CMFD)
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: MQN
Dated: March 31, 2017
Received: April 3, 2017

Dear Nicholas 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.

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*

K162594

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 mandibular body and mandibular ramus where gradual bone distraction is required in adults and pediatric patients. DePuy Synthes CMF Distraction System is intended for single use only.

Mandible
- The 1.0 mm plates and screws are intended for neonates and infants under the age of 12 months
- The 1.3 mm plates and screws are intended for neonates, infants, and children 4 years of age and younger
- The 1.5 mm and 2.0 mm plates and screws are intended for infants, children, adolescents, and adults 1 year of age and older

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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SYNTHES®

5. 510(k) Summary

Date Prepared: April 24, 2017

5.1.Submitter

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5.2.Device

Name of Device: Craniomaxillofacial Distraction System (CMFD)
Common or Usual Name(s): External Mandibular Fixator and/or Distractor
Classification Name(s): Bone plate
Regulatory Class: Class II - 872.4760
Product Code: MQN

5.3.Predicate Devices

Primary Predicate Device:

- Synthes Craniomaxillofacial Distraction System (K060138)

Reference Device(s):

- Synthes Curvilinear Distraction System (K121502)

5.4.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 mandibular body and mandibular ramus where gradual bone distraction is required in adults and pediatric patients. DePuy Synthes CMF Distraction System is intended for single use only.

Mandible

- The 1.0 mm plates and screws are intended for neonates and infants under the age of 12 months
- The 1.3 mm plates and screws are intended for neonates, infants, and children 4 years of age and younger
- The 1.5 mm and 2.0 mm plates and screws are intended for infants, children, adolescents, and adults 1 year of age and older

5.5.Device Description

DePuy Synthes Craniomaxillofacial (CMF) Distraction System is a modular distractor system intended for correction and reconstruction of the mandibular body and mandibular ramus in adults, adolescents, children, infants, and neonates. The distractor implant consists of several components; the distractor body, footplates, extension arms, and bone screws, many of which are available in a variety of configurations to meet patient and surgeon needs as detailed the table below.

Component	Distractor Body	Footplates	Extension Arms	Bone Screws
Dimensions	10, 15, 20, 25, 30, 35, and 40 mm lengths	Cloverleaf, mesh, and elevated mesh designs Accept 1.0, 1.2, 1.3, 1.5, 1.7, 2.0, and 2.4 mm diameter screws	Rigid lengths are 20, 40, and 60 mm Flexible lengths are 30, 40, and 60 mm	1.0, 1.2, 1.3, 1.5, 1.7, 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 either percutaneously or intra-orally.

5.6.Comparison to Predicate Devices

Indications:

In the previous clearance of CMFD (K060138), the indications for use were separated by the naming convention "CMF Distraction System" and "Pediatric CMF Distraction System" where the 1.0 mm and 1.3 mm plates and screws were considered the Pediatric CMF Distraction System and the 1.5 mm and 2.0 mm plates and screws were considered the CMF Distraction System. In this submission, the indications for use statement was altered to detail the exact age range applicable to each plate and screw size to ensure clarity in the pediatric use of the device, and to ensure the use of 1.3 mm plates and screws was aligned with the Synthes Curvilinear Distractor (K121502) to include children 4 years of age and younger. No other changes were made to the indications for use since the previous clearance of CMFD (K060138). CMFD remains intended for correction of deformities and post-traumatic defects of the mandible through gradual bone distraction in both adult and pediatric patients. The changes to the indications for use since the previous clearance do not raise any new questions of safety and efficacy and do not result in a new intended use not already addressed by the predicate devices.

Technology

Technological Similarities of the subject Craniomaxillofacial Distraction System (CMFD) to CMFD (K060138):

In comparison to the previously cleared design of CMFD (K060138), the principle design and function of the device remains unchanged. The distractor system consists of a distractor body, extension arms, footplates, screws, and instruments. Footplates are assembled to the distractor body and fixation of the footplates to bone is accomplished using screws. Distraction of the bone is accomplished by the surgeon, patient, and/or patient caregiver using an instrument to drive the advancement/lead screw in the distractor body. Rotation of the advancement/lead screw translates the footplates and distracts the bones.

Technological Differences of the subject Craniomaxillofacial Distraction System (CMFD) to CMFD (K060138):

In comparison to the previously cleared design of CMFD (K060138), the redesigned CMFD distractor bodies feature a spring clip mechanism to prevent reversing of the device due to patient movement. Components of the distractor body assembly were changed accordingly to accommodate the spring clip mechanism. Changes include material and dimensional changes. The design changes were made to address the root-cause of recall Z-2148-2014. Non-clinical performance data provided in the submission is detailed below in **Section 5.7**, and demonstrates that the differences in technological characteristics of the subject and predicate device do not raise new questions of safety and efficacy.

5.7.Non-clinical performance data

Non-clinical performance data demonstrates the modified distractor design is an effective correction of the root-cause of the associated recall of the device – reversing due to patient movement:

- Anatomically simulated motion (i.e. swinging or spinning of the flexible extension arm during treatment) of the redesigned CMFD showed the device does not reverse unintentionally.

Non-clinical performance supports that the design of the subject CMFD System is substantially equivalent to the primary predicate device.

Mechanical:

- **Construct bending strength analysis** of the redesigned CMFD in comparison to the recalled design of CMFD demonstrates the design changes including material changes do not affect the strength of the distractor construct.
- **Torque Input/Force Output and construct torsional strength testing** demonstrates that the device is capable of outputting the force required to distract bone in the intended applications without failing. 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.
- And, the **construct tensile strength** of the redesigned CMFD meets the same human factors benchmark as the recalled CMFD. 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.
- **Engineering analysis** of Raised Head Screws in comparison to the predicate PlusDrive Screws from the Synthes Craniomaxillofacial Distraction System (K060138) demonstrates how the Raised Head Screws are expected to have equivalent performance **(Torsional Strength, Insertion Torque, Axial Pullout, and Construct Strength)** as the Plus Drive Screws when used with the Craniomaxillofacial Distraction System.

Biocompatibility:
Chemical characterization and cleanliness (ISO 10993-18) and cytotoxicity (ISO 10993-5) tests were performed to document that the manufacturing process has not fundamentally altered the composition and cleanliness of the final finished distractor bodies. All other subject devices utilize the same material and manufacturing methods as the previous design of CMFD (K060138) and therefore biocompatibility testing is not required for these devices in this submission.

Sterilization:
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 sterility validation of the subject devices was based on Master Products. Master Products are those possessing the most difficult challenges to sterilize via steam, establishing that proposed devices can be cleaned or sterilized considering worst-case conditions and design elements.

5.8.Clinical performance data

No clinical performance data is included in this submission.

5.9.Substantial Equivalence

The information provided in this submission demonstrates:

- The modified distractor design is an effective correction of the root-cause of the associated recall
- The proposed devices are at least as safe and effective as the predicates
- The proposed CMFD System has the same intended use as the predicate devices

The information provided in this submission supports substantial equivalence.