Stryker
Gregory Gohl
Sr. Regulatory Affairs Specialist
750 Trade Centre Way - Suite 200
Portage, Michigan 49002

September 11, 2018

Re: K181504
Trade/Device Name: Stryker Pediatric Mandibular Distractor 2
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: MQN
Dated: August 9, 2018
Received: August 13, 2018

Dear Gregory Gohl:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Mary S. Runner -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181504

Device Name
Stryker Pediatric Mandibular Distractor 2

Indications for Use *(Describe)*
The Stryker Pediatric Mandibular Distractor 2 is intended to be used for bone stabilization and lengthening of the mandibular body and ramus. The Stryker Pediatric Mandibular Distractor 2 is indicated to correct congenital or post traumatic defects in the body and ramus of the mandible of neonates and children up to 4 years old.

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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Section 5. 510(k) Summary

This section provides a summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER [§807.92(a)(1)]

510(k) Owner:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 79111 Freiburg, Germany
Submitter/ Contact Person:	Gregory Gohl Sr. Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-4319 Fax: 877-648-7114
Date Prepared:	August 9, 2018

II. DEVICE [§807.92(a)(2)]

Trade/Device Name:	Stryker Pediatric Mandibular Distractor 2
Abbreviated Name:	PMD 2
Classification Name:	”Bone plate” per 21 CFR 872.4760
Common or Usual Name:	External Mandibular Fixator and/or Distractor
Regulatory Class:	Class II
Product Code:	MQN
Regulation Medical Specialty and Review Panel	Dental

III. PREDICATE DEVICE [§807.92(a)(3)]

Stryker Pediatric Mandible Distractor – K133398

IV. DEVICE DESCRIPTION [§807.92(a)(4)]

The Stryker Pediatric Mandibular Distractor 2 (PMD 2) system is a distraction system consisting of the following major components: distractor with integrated footplates, integrated anti-reverse feature, removable activation rod, deactivation instrument, and a small activation handle/activation key. The distractor initially stabilizes and then gradually distracts the bone segments separated by osteotomy. The removable activation rod is connected to the distractor and provides the point of attachment for the external small activation handle/activation key used to initiate the distraction of the bone segments. The anti-reverse feature is deactivated with the corresponding deactivation instrument.

The Stryker Pediatric Mandibular Distractor 2 (subject device) includes the distractor body, integrated footplates, a sliding footplate, integrated anti-reverse feature, and the activation joint (to attach the activation rod). It is available in eight variants with two different distraction lengths (20 and 30 mm) and right or left footplate configuration with footplate sizes having either a 2X2 or 3X3 hole pattern.

V. INDICATIONS FOR USE [§807.92(a)(5)]

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE

	Subject Device	Predicate Device – K133398
Indications for Use	The Stryker Pediatric Mandibular Distractor 2 is intended to be used for bone stabilization and lengthening of the mandibular body and ramus. The Stryker Pediatric Mandibular Distractor 2 is indicated to correct congenital or post traumatic defects in the body and ramus of the mandible of neonates and children up to 4 years old.	The Stryker Pediatric Mandible Distractor is intended to be used for bone stabilization and lengthening of the mandibular body and ramus. The Stryker Pediatric Mandible Distractor is indicated to correct congenital or post traumatic defects in the body and ramus of the mandible of neonates and children up to 4 years old.

The subject device is indicated for use in the same anatomic areas as the predicate device and for the same surgical applications. There is no difference in the Indications for Use.

A. Intended Use

The Stryker Pediatric Mandibular Distractor 2 is intended to be used for bone stabilization and lengthening of the mandibular body and ramus.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [§807.92(a)(6)]

The Stryker Pediatric Mandibular Distractor 2 is compared to its predicate device for substantial equivalence based on the following criteria:

A. Principle of Operation
B. Technological and Operational Characteristics

A. Principle of Operation

The basic operational principle of the subject device, as well as, the predicate device is for bone stabilization and lengthening. The method of site preparation and fixation is the same for both the subject and predicate device. The subject device and predicate device are temporary implants.

B. Technological and Operational Characteristics

The Stryker Pediatric Mandibular Distractor 2 (PMD 2) is the second generation of the Stryker Pediatric Mandible Distractor (PMD) currently in the market. Hence, the PMD 2 is similar to its predicate device, PMD, having the following technological and operational characteristics:

- Material: Both the subject device and predicate device are made of biocompatible titanium according to standards.
    - The subject device is made of commercially pure titanium (CP Ti), stainless steel, nickel cobalt alloy, and aluminum oxide.
    - The predicate device is made of commercially pure titanium (CP Ti) and stainless steel
- Mode of Fixation: Implant fixation with screws is the same as the predicate device.
- Design: The design of the subject device is similar to the predicate device. They both have the same components: body, footplates, activation joint (for activation rod connection). In addition, the subject device uses the same components and interfaces (e.g. activation rod) for distraction activation as the predicate device. The

subject device and its predicate device offer various options of distraction lengths and footplate sizes. The footplates of the subject device and predicate device are fully integrated (i.e., non-welded). The subject device contains an integrated anti-reverse feature that uses a deactivation instrument to be deactivated compared to the predicate device, which does not.

- Packaging: The subject device is sterile, and the predicate device is dispensed non-sterile.

The table below compares the technological characteristics of the PMD 2 to the predicate device (Table 5-2).

TABLE 5-2 – TECHNOLOGICAL CHARACTERISTICS COMPARISON MATRIX OF SUBJECT PMD 2 TO THE PREDICATE

Feature	Subject Device	Predicate Device	Explanation of Differences
Principles of Operation	Mandibular Distraction Osteogenesis	Mandibular Distraction Osteogenesis	Identical
Mechanism of Action	The PMD 2 devices are fixated to the body or ramus of the mandible for mandibular lengthening or advancement	The PMD devices are fixated to the body or ramus of the mandible for mandibular lengthening or advancement	Identical
Mode of Fixation	Implant fixation with screws	Implant fixation with screws	Identical
Exemplary illustration of device			Identical except for the integrated anti-reverse feature
Design	• Components: Body, Integrated Footplates, Activation Joint, Integrated Anti-Reverse Feature • Distraction Lengths Options: 20 & 30 mm • Footplate Size Options: 2x2 & 3x3 • Low Height Profile: 4.3 mm • Screw Diameter: 1.7 & 1.9 mm • Advancement: 1 turn = 0.5 mm	• Components: Body, Integrated Footplates, Activation Joint • Distraction Lengths Options: 20 & 30 mm • Footplate Size Options: 2x2 & 3x3 • Low Height Profile: 4.3 mm • Screw Diameter: 1.7 & 1.9 mm • Advancement: 1 turn = 0.5 mm	Identical except for the integrated anti-reverse feature
Material	Titanium (Commercially Pure Titanium acc. ASTM F67) Stainless Steel Nickel Cobalt Alloy Aluminum Oxide	Titanium (Commercially Pure Titanium acc. ASTM F67) Stainless Steel	Similar. The additional materials are due to the anti-reverse feature
Packaging	Sterile	Non-sterile	Different due to the need to fulfill sterile product European market requirements

Overall, any changes do not alter the subject device significantly, and do not represent a new worst case in design.

VII. PERFORMANCE DATA [§807.92(b)(1)]

The Stryker Pediatric Mandibular Distractor 2 was subjected to non-clinical testing including verification and validation testing of biocompatibility, manufacturing cleaning, gamma sterilization, corrosion resistance, dynamic compression-tensile force, distraction force, anti-reverse feature functionality and torque to failure, blood influence, design validation – end user test, and shelf life (aging and packaging). The system passed all tests.

Specifically, the following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the PMD 2 system was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process'", issued June 16, 2016, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by the FDA. The tests supported the biocompatibility of the device.

The implant is mainly made from commercially pure titanium (CP Ti), which conforms to ASTM F67 for chemical composition, the same as the predicate device. Cytotoxicity testing was performed using DIN EN 10993-5:2009, *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*. Corrosion testing was performed using internal instruction DQI 30-022, *Implant Corrosion Testing, Stryker Trauma & Extremities, 2017*. The tests supported the biocompatibility of the device.

Performance Bench Testing

The following performance bench tests were completed:

TABLE 5-3: PERFORMANCE BENCH TESTS

Characteristic	Tests	Test Methods	Results
Biocompatibility	Cytotoxicity	Verify biocompatibility in regards to cytotoxicity through in vitro indirect extract tests per ISO-10993-5 and ISO 10993-12	Acceptance criterion were met; tests were passed.
	GC/MS Fingerprint	Verify biocompatibility in regards to GC/Fingerprint through in vitro indirect extract tests per ISO-10993-18 and ISO 10993-12	Acceptance criterion were met; tests were passed.
	Corrosion	Verify corrosion behavior of implant and instruments	Corrosion resistance was proven; tests were passed.
Performance	Dynamic Compression and Tensile Force	Verify that unintended movement of the sliding footplate is properly prevented with an activated "anti-reverse" mechanism.	Acceptance criterion were met; tests were passed.
	Distraction Force	Verify the distraction force and the ability of small activation handle to transmit sufficient torque.	Acceptance criterion were met; tests were passed.
	Anti-Reverse Mechanism Functionality	Verify that activation and deactivation of the anti-reverse feature is possible within shelf life.	Acceptance criterion were met; tests were passed.
	Torque to Failure of Anti-Reverse Mechanism	Verify that the torque to failure is high enough that the resistance caused by turning against the activated anti-reverse mechanism is recognizable by the user before breakage.	Acceptance criterion were met; tests were passed.
	Deactivation Instrument Lifetime Usage	Verify that deactivation of "anti-reverse" feature is always possible with the deactivation instrument within its lifetime usage.	Acceptance criterion were met; tests were passed.

Characteristic	Tests	Test Methods	Results
	Effect of Blood Contact on Anti-Reverse Mechanism Functionality	Verify that the functionality of the anti-reverse feature is given after contact with blood	Acceptance criterion were met; tests were passed.
	End User Validation	Validate that the end user needs of the PMD 2 system are fulfilled	Acceptance criterion were met; tests were passed
Shelf Life	Aging	Verify that the device, including the anti-reverse feature, maintains properties and characteristics within shelf life.	Acceptance criterion were met; tests were passed.
	Sterile Packaging	Simulation of handling and transportation from Stryker's stock to end customer and investigation of the integrity of the packaging system, following ISO 11607-1 and ASTM D4169	Acceptance criterion were met; tests were passed.
Sterilization	Gamma Sterilization Validation	VD_{max}^{25} Method for substantiation of 25 kGy as sterilization dose according to ISO 11137-1, -2 and -3 for multiple production batches for verifying compliance with EN 556 to achieve a SAL 10^{-6}. Microbiological Testing Methods to verify the suitability of the microbiological test methods used for the bioburden determination and sterility testing for the subsequently planned verification experiment to validate gamma sterilization in accordance to ISO 11737-1 and -2.	Method Validated

Overall, the results of the performance bench tests support the substantial equivalence of the subject device.

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing [§807.92(b)(2)]

Clinical testing was not required as a basis for substantial equivalence.

VIII. CONCLUSIONS [§807.92(b)(3)]

The Stryker Pediatric Mandibular Distractor 2 is substantially equivalent to its predicate device with respect to its intended use, design, materials, and operational principle. The results of the non-clinical data demonstrate the Stryker Pediatric Mandibular Distractor 2 will perform as intended in the specified use conditions. Further, the performance testing confirms that the Stryker Pediatric Mandibular Distractor 2 is safe and effective for its intended use, and it performs as well as the predicate device. According to the comparison based on the requirements of 21 CFR 807.92 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.