Stryker Leibinger GmbH & Co. KG
Gregory Gohl
Senior Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, D-79111 DEU
Germany

8/5/2023

Re: K230733
Trade/Device Name: Stryker Resorbable Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: April 27, 2023
Received: July 7, 2023

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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.

K230733

Device Name
Stryker Delta Resorbable Fixation System

Indications for Use *(Describe)*

Dental
The self-tapping screws and low profile emergency screws are intended for use in the fixation of bones of the maxillofacial and midfacial skeleton affected by trauma or for reconstruction, and can be used in pediatric patients older than 29 days and up to two (2) years of age (infants). The self-tapping screws and low profile emergency screws are designed to be compatible with the components (plates, meshes) of the Delta Resorbable Fixation System K213777.

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 D-79111 Freiburg, Germany
Submitter / Contact Person:	Gregory Gohl Sr. Regulatory Affairs Specialist Stryker Craniomaxillofacial (CMF) 1941 Stryker Way Portage, MI 49002 Phone: 269-370-1476
Date prepared:	August 5, 2023

II. DEVICE [§807.92(a)(2)]

Trade Name:	Stryker Resorbable Fixation System
Abbreviated Name:	Delta System / Delta Resorbable Fixation System
Common or Usual Name:	Resorbable Bone Plating System
Device:	Stryker Resorbable Fixation System
Classification Name & Regulation Description:	Plate, Bone; per 21 CFR §872.4760
Regulation Medical Specialty & Review Panel:	Dental (OHT1/DHT1B – Office of Ophthalmic, Anesthesia, Respiratory, ENT, & Dental)
Primary Product Code:	JEY
Subsequent Prod. Codes:	DZL
Regulatory Device Class:	Class II
*Note the company Stryker or legacy name Stryker Leibinger precedes the product/trade name and predicate device in some documentation.	

III. PREDICATE DEVICE [§807.92(a)(3)]

A. Predicate Device: Stryker Resorbable Fixation System – K213777

1 Submission Branch of Predicate Device: Dental (OHT1/DHT1B – Office of Ophthalmic, Anesthesia, Respiratory, ENT, & Dental); Neurology (OHT5/DHT5A – Office of Neurological and Physical Medicine Devices) [bundled]

B. Reference/Secondary Device: Stryker MMF Screw – K050535

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

A. Submission Branch of Subject Device: Dental (OHT1/DHT1B – Office of Ophthalmic, Anesthesia, Respiratory, ENT, & Dental)

B. Subject Device: Stryker Resorbable Fixation System (also referred to as Delta System or Stryker Delta Resorbable Fixation System; marketed as DualStart)

The subject devices, the Delta System self-tapping screw (STS) and low profile emergency screw (LPES), are intended for use in the fixation of bones of the maxillofacial and midfacial skeleton, affected by trauma or for reconstruction. The subject device can be used in pediatric patients older than 29 days and up to two (2) years of age (infants), but is not intended for use in the mandible and/or full load bearing procedures.

The scope of this submission covers the addition of the subject device screws to the previously cleared Delta System. Through this submission there is no change to the existing articles within the Delta System. The subject device screws are designed to be compatible with the existing components of the Delta System (plates, meshes), which have been previously cleared through K213777. Compared to the original Delta System, the subject STS and LPES have a limited patient population of pediatric patients older than 29 days and up to two (2) years of age (infants).

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

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE AND RELATED

Feature	Predicate Device	Subject Devices (only)	Explanation of Differences
Indications for Use (subject devices only)	Dental The Delta Resorbable Fixation System is intended for use in the fixation of bones of the maxillofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients.	Dental The self-tapping screws and low profile emergency screws are intended for use in the fixation of bones of the maxillofacial and midfacial skeleton affected by trauma or for reconstruction, and can be used in pediatric patients older than 29 days and up to two (2) years of age (infants). The self-tapping screws and low profile emergency screws are designed to be compatible with the components (plates, meshes) of the Delta Resorbable Fixation System K213777.	For subject device STS and LPES screws, only, restriction of patient population to pediatric patients older than 29 days and up to two (2) years of age (infants)
Area of Application	maxillofacial and midface	maxillofacial and midface	Identical
Patient Contact, Duration of Implantation within Body	Tissue/Bone, Permanent	Tissue/Bone, Permanent	Identical

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

The subject device is compared to its predicate device (and the reference device due to the Delta System screws - DZL) for substantial equivalence of technological characteristics based on the criteria of pilot hole preparation process flow, geometrical modifications, and patient population.

The technological characteristics of the subject device that remain the same as the predicate device include material of construction, manufacturing process, sterilization process, packaging materials, and anatomical area indication.

A. Pilot Hole Preparation Process Flow

The operational principle of the previously cleared Stryker Resorbable Fixation System is a cranio-maxillofacial plating system intended for use in the fixation of bones of the maxillofacial and midfacial skeleton, affected by trauma or for reconstruction. The method of pilot hole preparation has been modified for the self-tapping screw (STS) subject device. The predicate system requires pre-drilling and pre-tapping of the pilot hole prior to insertion. The STS subject screws require only pre-drilling of the pilot hole prior to screw insertion, thus removing the pre-tapping step. No modifications of principles of operation are made to the low profile emergency screw (LPES) subject device.

B. Geometry Modifications

The subject devices incorporate a modification to the geometry to support the mechanical functionality of a self-tapping screw. Modifications to the subject devices include the thread geometry and screw head dimensions. The interfaces for the subject screws have been reviewed, confirming there is no impact to the intended product interfaces of the subject screws as compared to the predicate screws.

C. Patient Population

The subject devices, the self-tapping screw and low profile emergency screw, have a limited patient population of pediatric patients older than 29 days and up to two (2) years of age (infants), compared to the predicate device Delta System, which has a patient population of adults and a pediatric population to include neonate, infant, children, and adolescent patients.

D. Materials

As mentioned before, there is no change in material between the subject devices and the predicate device products. Implants are made of a copolymer of poly lactide and poly glycolide.

E Dimensions

The subject devices, the self-tapping screw and low profile emergency screw, have limited modifications to the dimensions, as described in the above geometry modifications. A comparison of length and diameter are shown in the table below.

TABLE 5-2: COMPARISON OF DIMENSIONS

Dimension	Predicate Device	Subject Devices (only)	Explanation of Differences
Length	3mm – 10mm	3mm – 6mm	Reduced screw length offering for the subject devices.
Diameter	2.2 mm (non-emergency screw) 2.6mm (emergency screw)	2.2 mm (non-emergency screw) 2.6mm (emergency screw)	Identical

VII. PERFORMANCE DATA [§807.92(b)(7)]

The modifications for the subject devices in this submission include a limited patient population of pediatric patients older than 29 days and up to two (2) years of age (infants), removal of the tapping step from pilot hole preparation (self-tapping screw [STS] only), and screw geometry. The limited patient population was determined based on a business decision, focusing new product introduction on our primary customer and patient base, of pediatric patients older than 29 days and up to two (2) years of age (infants). Verification and validation testing protocols were constructed to ensure testing captured this specific limited patient population, in accordance with the FDA 2014 guidance Premarket Assessment of Pediatric Medical Devices.

The material of construction, manufacturing process, sterilization process, and packaging materials remain unchanged compared to the predicate, therefore biocompatibility testing, shelf life testing, and sterilization testing were leveraged from the predicate system (K213777). Bioburden tests were performed to further affirm no new worst-case is introduced with the modified screw geometries, which concluded a passing result.

Verification test criteria and methods were identified to evaluate the performance of the subject screws according to the proposed limited patient population of pediatric patients older than 29 days and up to two (2) years of age (infants). Modification of the operating principle, pilot hole preparation, for the STS was additionally evaluated through performance testing. The impact of screw geometry modification on material properties during real-time degradation was evaluated. The following performance tests were performed to support the substantial equivalence determination of the subject screws to the predicate based on the modifications described:

TABLE 5-2: PERFORMANCE BENCH TESTING

Characteristic	Test	Result	Standards
Verification test	Insertion test	Passed	ASTM F2502
Verification test	Shear testing	Passed	ASTM F2502
Verification test after real-time degradation	Pull-out test	Passed	ASTM F2502
Verification test after real-time degradation	Inherent viscosity	Passed	ASTM F2502

The objective of insertion testing and shear-off testing is to show mechanical stability of the subject device screws during insertion. The objective of the pull-out testing is to demonstrate the subject device screws have sufficient retention in bone, or tensile strength, over the bone healing time, simulated through real time degradation. The objective of IV measurements was to

measure the initial IV measurement and confirm that the geometry and process did not influence the starting molecular weight and thus the potential degradation properties of the subject device when compared to the predicate device. All verification testing concluded passing results.

A risk analysis and user validation testing-were performed. The validation study was constructed to confirm use error is under control, a comprehension of the Instructions for Use (IFU) is understood, and user needs are met. With respect to the modifications made to the subject devices, the validation evaluated the usability of the workflow steps, functionality of the devices, compatibility of related products or processes, and knowledge comprehension of labeling and IFU. Specifically, the knowledge comprehension addressed the ability to comprehend the modification to the pilot hole preparation and the limitation to the patient population. The validation testing concluded a passing result based on the data collected and reviewed in the study.

Performance Bench Testing

Performance bench testing was performed in the form of verification testing to confirm substantial equivalence. See Table 5-2.

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. CONCLUSION [§807.92(b)(3)]

In summary, the Stryker self-tapping screw (DualStart Screw) and low profile emergency screw additions to the Stryker Resorbable Fixation System is substantially equivalent to its predicate device. The modifications proposed for the subject devices include the removal of a pilot hole preparation step (STS only), screw geometry modification, and restriction of the patient population. The material of construction, sterilization process, manufacturing process, packaging components, and anatomical area intended use / indication remain unchanged and identical to the predicate system. The scope of modifications concludes no impact to biocompatibility, sterilization, and shelf life. The performance verification testing supports that the performance of the subject screws is substantially equivalent to the predicate. Overall, the modifications do not raise new questions of safety or effectiveness. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence to the predicate device.