Stryker Leibinger Micro Implants
Gregory Gohl
Senior Regulatory Affairs Specialist
750 Trade Centre Way -Suite 200
Portage, Michigan 49002

2/4/2022

Re: K213777
Trade/Device Name: Stryker Resorbable Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, GXR, HBW
Dated: January 21, 2022
Received: January 26, 2022

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,

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.

510(k) Number *(if known)*

K213777

Device Name
Stryker Delta Resorbable Fixation System

Indications for Use *(Describe)*

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.

Neuro: The Delta Resorbable Fixation System is intended for use in the fixation of bones of the cranial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 Fax: 877-648-7114
Date prepared:	February 4, 2022

II. DEVICE [§807.92(a)(2)] - K213777

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, Fixation, Bone; per 21 CFR §888.3030
Regulation Medical Specialty & Review Panel:	Dental (OHT1/DHT1B – Office of Ophthalmic, Anesthesia, Respiratory, ENT, & Dental); Neurology (OHT5/DHT5A – Office of Neurological and Physical Medicine Devices)
Primary Product Code:	JEY
Subsequent Prod. Codes:	GXR, HBW
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. Submission Branch of Predicate Device: Division of Surgical, Orthopedic, and Restorative Devices; Office of Device Evaluation Center for Devices and Radiological Health

B. Predicate Device: Stryker Resorbable Fixation System - K113109

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

A. Submission Branch of Subject Device: Dental (OHT1/DHT1B – Office of Ophthalmic, Anesthesia, Respiratory, ENT, & Dental); Neurology (OHT5/DHT5A – Office of Neurological and Physical Medicine Devices)

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

The Stryker Resorbable Fixation System is a cranio-maxillofacial plating system intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients but is not intended for use in the mandible and/or full load bearing procedures. It consists of resorbable bone fixation plates, meshes, and screws made of a copolymer of poly lactide and poly glycolide.

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

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE

	Predicate Device – K113109	Subject Device
Indications for Use	The Delta Resorbable Fixation System is intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients but is not intended for use in the mandible and/or full load bearing procedures.	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. Neuro: The Delta Resorbable Fixation System is intended for use in the fixation of bones of the cranial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients.

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

The subject device is compared to its predicate device for substantial equivalence of technological characteristics based on the following criteria:

A. Principles of Operation
B. Technological Characteristics

C. Principles of Operation / Operating Principle

The basic operational principle of the Stryker Resorbable Fixation System remains the same as for the predicate: The Delta Resorbable Fixation System is intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients but is not intended for use in the mandible and/or full load bearing procedures. This submission does not propose a change in the operating principle as there is no change to the implant design, interface with accessories or implant materials.

D. Technological Characteristics

The technological characteristics remain the same as the predicate:

- Same Intended Use: The Delta Resorbable Fixation System is intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients but is not intended for use in the mandible and/or full load bearing procedures.
- Same Mode of Fixation: fixated to the native bone with Stryker Delta Resorbable screws.
- Same Materials of Construction: Implants are made of a copolymer of poly lactide and poly glycolide. No change to the formulation of the polymer.
- Same Design: The change of the sterilization supplier and location does not change the implant design by any means.

VII. PERFORMANCE DATA [§807.92(b)(7)]

The modifications described in this submission are the change to a new Ethylene Oxide (EO) sterilization supplier and location and a modification to the packaging. The new EO sterilization cycle is equivalent to the predicate device sterilization cycle operating at lower EO gas concentrations. There is no change to the sterilization method regarding the final end-product. The new supplier location and cycle were proven to be as substantially equivalent for sterilization as the predicate location.

Packaging components, design, and materials remain the same. Labeling requirements also remain unchanged. The modification of the packaging is an update of the sterile barrier layout of the double pouch packaging system (i.e., only the inner pouch is the sterile barrier instead of the outer and inner pouch as for the predicate devices). This change is

communicated to the customer through an inclusion of a warning sticker in regard. Useability validation confirms the warning sticker label mitigates the risk associated with the change in the sterile barrier packaging.

A risk analysis was performed, and sterilization testing was performed in support of the substantial equivalence determination.

There is no change in the design, material, manufacturing process, or duration/location of contact. The tests necessary to evaluate the change regarding the new sterilization location and supplier are listed below. The following tests were performed to adopt the Stryker Resorbable Fixation System plates and meshes into the existing EO Cycle.

TABLE 5-2: STERILIZATION AND BIOCOMPATIBILITY TESTING

Characteristic	Test	Result	Standards
Sterilization Validation	Product Adoption and Sterility	Passed	ISO 11135:2014 +AMD1:2018
Sterilization / Biocompatibility	EO Residual	Passed	ISO 10993-7:2008 +AMD1:2019
Sterilization / Biocompatibility	Endotoxin Testing	Passed	ISO 10993-1 +ANSI/AAMI ST72:2019

The aseptic transfer (i.e., the transfer of the devices from the non-sterile field into the sterile field during surgery) is modified by the change in the sterile barrier declaration. The aseptic transfer has been identified as the only critical task to be subjected to a summative usability validation of packaging. The human factors testing/study was designed to evaluate in particular possible adverse effects caused by negative transfer. The study was conducted with a sample size of 19 representative users including experienced as well as new users. The full packaging configuration was subjected to test. All test participants were able to perform the aseptic transfer correctly. No use errors or use difficulties were observed. The packaging change was evaluated to be non-critical.

TABLE 5-3: SUMMATIVE USABILITY VALIDATION OF PACKAGING

Characteristic	Test	Result
Summative Validation	Aseptic transfer performance	Passed

Performance Bench Testing

Performance bench testing was not required as a basis for substantial equivalence.

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 Resorbable Fixation System is substantially equivalent to its predicate device. The design of implants has not changed, nor has the manufacturing of them changed. There is no change to the sterilization method, and the sterilization cycles of the subject and predicate device are evaluated to be equivalent throughout this submission. The fundamental scientific technology has not changed from the predicate device since the design of the implants or subcomponents has not changed. The intended use, principle of operation, mechanism of action, technological characteristics, and materials of construction also have not changed. In reference to packaging and labeling, specifically, the packaging components, design, and materials remain the same. The moisture barrier change in packaging of the subject devices led to change in labeling. Human factors data supports that the modified packaging, including the change in labeling, 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.