August 14, 2023

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

Re: K231208
Trade/Device Name: Stryker Resorbable Fixation System
Regulation Number: 21 CFR 882.5360
Regulation Name: Cranioplasty Plate Fastener
Regulatory Class: Class II
Product Code: HBW
Dated: May 19, 2023
Received: July 14, 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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.08.14 10:22:50 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231208

Device Name
Stryker Resorbable Fixation System

Indications for Use *(Describe)*
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.

The self-tapping screws and low profile emergency screws are intended for use in the fixation of bones of the cranial 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).

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 14, 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:	Fastener, Plate, Cranioplasty; per 21 CFR §882.5360
Regulation Medical Specialty & Review Panel:	Neurology (OHT5/DHT5A – Office of Neurological, Neurointerventional, and Neurodiagnostic Devices)
Primary Product Code:	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. Predicate Device: Stryker Universal Neuro III System AXS Screw – K171152

B. Reference Device: Stryker Resorbable Fixation System – K213777

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

A. Submission Branch of Subject Device: Neurology (OHT5/DHT5A – Office of Neurological, Neurointerventional, and Neurodiagnostic Devices)

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

The predicate Stryker Universal Neuro III System is intended for reconstruction, stabilization, and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy, and cranial features in adults and adolescents (age 12 and higher). The reference device 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 reference device 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.

Through this submission there is no change to the existing articles within the Delta System. The scope of this submission covers the addition of screws to the Delta System, which are shown as a modification of screws of the reference device to create the addition of self-tapping screws (STS) and low profile emergency screws (LPES). The subject STS and LPES, only, 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)]

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.

The self-tapping screws and low profile emergency screws are intended for use in the fixation of bones of the cranial 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).

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE (PREDICATE)

Feature	Predicate Device	Subject Devices (only)	Explanation of Differences
Indications for Use	The Stryker Universal Neuro III System is intended for reconstruction, stabilization, and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy, and cranial fractures in adults and adolescents (age 12 and higher).	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.	Similar .

TABLE 5-2: COMPARISON OF INDICATIONS FOR USE AND RELATED REFERENCE DEVICE)

Feature	Reference Device	Subject Devices (only)	Explanation of Differences
Indications for Use (overall Delta System)	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.	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.	Identical
Indications for Use (subject devices only)		Neuro The self-tapping screws and low profile emergency screws are intended for use in the fixation of bones of the cranial 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).	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	Craniofacial and midface	Craniofacial 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 and reference device system 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 reference 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 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 method of pilot hole preparation has been modified for the self-tapping screw (STS) subject device. The reference device 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 reference device screws.

C. Patient Population

The subject devices have a limited patient population of pediatric patients older than 29 days and up to two (2) years of age (infants), compared to the reference device Delta System, which has a patient population of adults and pediatric patients.

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 reference device, therefore biocompatibility testing, shelf life testing, and sterilization testing are out of scope of this submission, and adopted from the reference device system. 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 and reference device system based on the modifications described:

TABLE 5-2: PERFORMANCE BENCH TESTING

Characteristic	Test	Result	Standards
Verification test	Insertion test	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

A risk analysis was performed, and user validation testing, which also included human factors and usability engineering, in accordance with the FDA 2016 guidance Applying Human Factors and Usability Engineering to Medical Devices, was performed in support of the substantial equivalence determination. 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.

TABLE 5-3: USABILITY VALIDATION TESTING

Characteristic	Test	Result
Usability validation	Task performance (evaluated for use error)	Passed
Usability validation	Knowledge tasks	Passed
Usability validation	Rating questions after task performance	Passed

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 Resorbable Fixation System is substantially equivalent to the predicate and to the reference device system. 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 reference device 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 reference device. The user validation study, which also considered human factors and usability engineering, confirmed use error is under control, a comprehension of the IFU is understood, and user needs are met, all of which supports the determination of substantial equivalence to the predicate and reference device system. 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 and reference device system.