Stryker Craniomaxillofacial
Jonathan Schell
Sr Staff RA Specialist
1941 Stryker Way
Portage, Michigan 49002

January 13, 2024

Re: K232350
Trade/Device Name: Stryker Facial iD System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: August 04, 2023
Received: December 21, 2023

Dear Jonathan Schell:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232350

Device Name
Stryker Facial iD System

Indications for Use *(Describe)*
The Stryker Facial iD System is intended for osteotomy, stabilization and rigid fixation of maxillofacial fractures and reconstruction in adults and adolescents (age 12 and higher).

Specific Indications for Use:
- Orbital reconstructive/ trauma surgery

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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K232350

510(k) Summary

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

I. SUBMITTER

510(k) Owner:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Jonathan Schell, RAC Sr. Staff Regulatory Affairs Specialist Stryker Craniomaxillofacial 1941 Stryker Way Portage, MI, 49002 Phone: 484-889-5804 Fax: 877-648-7114
Date prepared:	January 13, 2024

II. DEVICE

Trade Name:	Stryker Facial iD System
Common or Usual name:	Bone Plating System
Classification name:	Bone Plate; 21 CFR §872.4760
Regulatory Class:	Class II
Product Code:	JEY

III. PREDICATE DEVICE

Predicate Device: K210731, KLS Martin Individual Patient Solutions

Reference Devices: K193143, Stryker Facial iD Plating System; K221855, Stryker Universal CMF System; K142568 Stryker MEDPOR TITAN 3D Orbital Floor Implant; K173039 TruMatch CMF Titanium 3D Printed Implant

IV. SUBJECT DEVICE DESCRIPTION

The Stryker Facial iD System (Subject Device) is intended for osteotomy, stabilization and rigid fixation of maxillofacial fractures and reconstruction in adults and adolescents (age 12 and higher), with the specific Indications for Use in orbital reconstructive and/or trauma surgery. The Subject Device is not intended for use in the orbital roof and can only be used if no exposure of the intracranial compartment is presented, and not intended for cranial use.

The Subject Device implants are additively manufactured patient-specific implants, and the patient-specific design of the implants allows certain features to be configured to meet the individual needs of each patient. The Subject Device implants are provided with a Design Proposal, an electronic Instruction for Use (IFU) and an optional Anatomical Model. Additionally, the Subject Device is compatible with a separately provided Customized Surgical Guides, Templates and Anatomical Models.

V. INDICATIONS FOR USE

Table 5- 1: Comparison of Intended Use/Indications For Use.

	Subject Device	Predicate Device K210731
Intended Use/Indication for Use	The Stryker Facial iD System is intended for osteotomy, stabilization and rigid fixation of maxillofacial fractures and reconstruction in adults and adolescents (age 12 and higher). Specific Indication for Use: Orbital reconstructive / trauma surgery	KLS Martin Individual Patient Solutions (IPS) is intended as a pre-operative software tool for simulating / evaluating surgical treatment options as a software and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the IPS software and the result is an output data file that may then be provided as digital models or used as input in an additive manufacturing portion of the system that produces physical outputs

		including implants, anatomical models, guides, splints, and case reports for use in maxillofacial, midface, & mandibular surgery. KLS Martin Individual Patient Solutions (IPS) implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in children (2 years of age to < 12 years of age), adolescents (12 years of age – 21 years of age), and adults.

The overall Intended Uses and the specific Indication for Use of the Subject Device and Predicate Device (K210731) cover the identical Intended Use and a similar indications for use. The Indications for Use are similar in that the Subject Device target population is a subset within the cleared Predicate Device (K210731) target population, but the area of application, patient contact, duration of implantation within body are all identical between the Subject and Predicate Device (K210731). Therefore, substantial equivalence is shown between the Subject Device and Predicate Device (K210731), and the reference devices (K193143, K221855, K142568, K173039) provide further support to allow a substantial equivalence decision.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject Device is compared to the Predicate Device for substantial equivalence of technological characteristics based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The operating principle for the Subject Device is to reconstruct, stabilize and/or provide rigid fixation in the maxillofacial anatomy (orbital and surrounding anatomy, excluding the orbital roof).

B. Technological Characteristics

The technological characteristics in regard to the principal of operation, patient-specific aspect, commercially pure titanium material, additive manufacturing method, non-sterility and sterilization method are identical when comparing the Subject and Predicate Device.

The implant thicknesses vary slightly when comparing the Subject Device to the Predicate Device, however the thickness in the area of the orbital region is identical.

Both the Subject and Predicate devices are fixated with screws of similar dimensions. The Subject Device is compatible with 1.2 and 1.7mm screws from the Stryker Upper-Face and the Stryker Mid-Face (K172572, K022185 and K221855). These devices are only be used within the anatomical locations and surgical protocol methods as originally FDA-cleared.

The minimal and maximal dimensions of the Subject Device result from mandatory design features as well as from specifications. The dimensions of the Subject Device (e.g. minimum width) is similar compared to the Predicate Device (K210731) and Reference Devices (K193143, K221855). The Subject Device is not a new worst-case scenario.

In addition to some dimensions, the difference between the Subject and the Predicate Device is the implant surface. Both devices offer a perforated surface, with the Subject Device also offering a solid or combined (solid and perforated in one implant) surface. The technological difference between the use of non-mesh/ non-perforated implants, and clinical performance of (non-perforated) commercially pure titanium orbital implants, has been mitigated through labeling and was compared to a similar reference device (K142568). When reviewing the Design Proposal, the surgeon should carefully consider the design of the orbital implant(s) and the operative plan (e.g., incorporation of drainage holes, or use of multiple implants or surgical drains) to facilitate adequate postoperative drainage of blood and fluids from the orbital space.

Although the porous structure of MEDPOR TITAN 3D Orbital Floor implant (K142568) is porous in the structural sense, it is not permeable to liquids - just like the solid commercially pure titanium implant, and since the MEDPOR TITAN 3D Orbital Floor implant (K142568) is indicated for orbital reconstruction in the orbital floor area, it can be used in comparison to the Subject Device.

A comparison table of the subject, predicate (K210731), and reference devices (K193143, K221855, K142568, K173039) is provided below:

Feature	Subject Device	**Predicate Device** KLS Martin Individual Patient Solutions (K210731)	**Reference Device** Stryker Facial iD Plating System (K193143)	**Reference Device** Stryker Universal CMF System (K221855)	**Reference Device** Stryker MEDPOR TITAN 3D Orbital Floor Implant (K142568)	**Reference Device** TruMatch CMF Titanium 3D Printed Implant (K173039)
Principle of Operation	The principle of operation for the Subject Device is to reconstruct, stabilize and/or provide rigid fixation in the maxillofacial anatomy.	The principle of operation for the Predicate Device is to reconstruct, stabilize and/or provide rigid fixation in the maxillofacial anatomy.				
Patient-specific	Yes, manufactured based on patient CT scan	Yes, manufactured based on patient CT scan	Yes, manufactured based on patient CT scan			Yes, manufactured based on patient CT scan
Material	Commercially pure titanium	CP Titanium or Ti-6Al-4V	Commercially pure titanium			Commercially pure titanium
Manufacturing Method	Additive Manufacturing	Additive, Selective Laser & Traditional	Additive Manufacturing			Additive Manufacturing
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)			
Implant Thickness	0.3 mm (not permitted in the midface area when a fracture needs to be bridged and is only allowed for inner orbital reconstruction.) 0.6 mm 0.9 mm	Orbital: 0.3 mm – 1.0 mm Maxillofacial / midface reconstruction: 0.6 mm – 10 mm	Midface: 0.8 mm – 1.5mm	Orbital, Upper- & Midface: 0.3 – 0.8 mm		
Implant Surface	Perforated/ Meshed Solid Combined	Perforated/Mesh	Solid	Perforated/Mesh, Solid for plates	Solid (porous MEDPOR side with a non-porous barrier sheet on orbit facing side)	
Number of Screw Holes	Min: ≥ 2 per side of defect Max: ≤ 50 per implant	Orbital, Mandibular, Maxillofacial /Midface: ≥2 per side of defect	Min: ≥ 2 per side of defect Max: ≤ 50 per implant	Min: ≥ 2 per side of defect		
Screw Diameter	1.2 mm 1.7 mm	Orbital: 1.5 mm Maxillofacial / midface: 1.5 mm – 2.3 mm		Upper-Face: 1.2 mm Mid-Face:1.7 mm		

Feature	Subject Device	**Predicate Device** KLS Martin Individual Patient Solutions (K210731)	**Reference Device** Stryker Facial iD Plating System (K193143)	**Reference Device** Stryker Universal CMF System (K221855)	**Reference Device** Stryker MEDPOR TITAN 3D Orbital Floor Implant (K142568)	**Reference Device** TruMatch CMF Titanium 3D Printed Implant (K173039)
Screw Length	3 mm – 12 mm	Orbital & Maxillofacial / midface: 3.5 mm – 22 mm		3 mm – 12 mm		
Screw Style	Head style: • Standard Design features: • Self-drilling • Self-tapping/Standard	Head style: • maxDrive • crossDrive Design features: • Drill-Free • Locking • ThreadLock TaperScrew TLTS • Standard	Head style: • Standard Design features: • Self-drilling • Self-tapping/Standard	Head style: • Standard Design features: • Self-drilling • Self-tapping/Standard		
Fixation Method	Stryker Universal CMF Screw Systems	KLS metallic bone screws for internal fixation of maxillofacial bones.	Stryker Universal CMF Screw Systems	Stryker Universal CMF Screw Systems		
Width (Screw-hole dependent)	Min: ≥ 4.0 mm (around screw holes) Min: ≥ 4.0 mm (not around screw hole)	Orbit: Min: ≥ 3.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole) Maxillofacial / midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole)				
Length	Min: 15.5 mm Max: 100 mm	Orbit: Min: 10.5 mm Max: 50 mm Maxillofacial / midface: Min 18 mm Max: 350 mm		Upper-Face & Mid-Face: Min: 9.35 mm (for 55-04231 2x2 Plate) Max: 116.7 mm (for 55-06734 2x34 Double Strip Plate)		Orbit/Midface: Min: 10 mm Max: 294mm
Degree of curvature (in-plane)	Min. radius: 0.25 mm	Orbital, Mandibular, Maxillofacial / Midface: Min: 30°	Min. radius: 0.25 mm	Min. radius: 0.2 mm		Orbit/Midface: 0°-12°/mm length

Feature	Subject Device	**Predicate Device** KLS Martin Individual Patient Solutions (K210731)	**Reference Device** Stryker Facial iD Plating System (K193143)	**Reference Device** Stryker Universal CMF System (K221855)	**Reference Device** Stryker MEDPOR TITAN 3D Orbital Floor Implant (K142568)	**Reference Device** TruMatch CMF Titanium 3D Printed Implant (K173039)
		Max: 180°				
Degree of curvature (out-of-plane)	Min. radius: 0.25 mm	Orbital, Mandibular, Maxillofacial / Midface: Min: 15° Max: 180°	Min. radius: 0.25 mm			Orbit/Midface: 0°-12°/mm length
Hole spacing	≥ 3.9 mm	Orbit: ≥ 3.5 mm Maxillofacial / midface: ≥ 4.5 mm	≥ 4.1 mm	≥ 3.0 mm (for 55-04424 Straight plate with 24 holes)		
Screw Hole Placement	Based on input from the surgeon and limited by the design restrictions from above.	Unknown	Based on input from the surgeon and limited by the design restrictions from above.	Based on plate		

VII. PERFORMANCE DATA

The following performance testing was conducted to show substantial equivalence:

The Subject Device is similar when compared to the Reference Device Stryker Facial iD System (K193143) for cleaning and sterilization validation. Biocompatibility testing was conducted on the Subject Device, which met the acceptance criteria, and the biocompatibility endpoints were evaluated in accordance with ISO 10993-1 and ISO 10993-5. The Subject Device implants are manufactured using the identical additive manufacturing process and the identical final material as the Reference Device (K193143).

Performance Bench Testing

Mechanical bench testing

The Subject Device performance testing was done in comparison to the Reference Devices (K221855) to demonstrate substantial equivalence. All tests have been performed with the corresponding worst-case design considering the entire design envelope and all design features. To demonstrate the mechanical performance a compression test as well as 4-point bending (acc. to ASTM F382) were performed to compare properties of the Subject Device against the previously cleared Reference Device (K221855) implants. The mechanical stability of the Subject Device was determined to be substantially equivalent to the Reference Devices (K221855).

Biocompatibility Testing

Biocompatibility was evaluated in accordance with ISO 10993-1 and cytotoxicity was evaluated in accordance with DIN EN ISO 10993-5 and DIN EN ISO 10993-12.

Based on the device categorization the respective endpoints for biological evaluation were addressed by testing and/or justifications. The results of biocompatibility testing conclude the Subject Device is biocompatible and meets the requirements of biocompatibility ISO standards.

The results of the cytotoxicity showed that the Subject Device implants demonstrated substantial equivalence with regards to cytotoxicity.

Cleaning & Sterilization

Cleaning and sterilization testing (acc. to DIN EN ISO 17664, ISO 17665-1, ISO 17665-2, ISO 14937) was conducted for the Subject Device and the acceptance criteria were met.

Steam sterilization validations were performed accordance with ISO 17665-1, ISO 17665-2 respectively ISO 14937 to a sterility assurance level (SAL) of 10-6 using the biological indicator (BI) overkill method. All test method acceptance criteria were met.

The end-user test validation of the Subject Device showed that the subject device is performing as intended in the specified use conditions. Therefore, the Subject Device met all pre-defined acceptance criteria, and the results of the performed tests show that no new risks regarding performance testing are raised with the Subject Device.

Animal Testing

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

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence. A risk mitigation assessment has been completed to demonstrate the safety and effectiveness for use of the Subject Device Facial iD system device in the intended patient population and with the given design features. The risk mitigation assessments have been completed based on FDA guidance, "Premarket Assessment of Pediatric Medical Devices," issued March 24, 2014, to demonstrate the substantial equivalence for of the subject devices in the indicated pediatric population (age 12 and higher). These risk assessments evaluated the following risk factors for pediatric patients: age, size, growth and development, body habitus, developmental milestones, pathophysiology, behavioral factors, psychosocial factors, human factors, surgical factors, and cumulative effects from repeat or unplanned radiation exposure (i.e., CT scan).

Major skeletal growth of the midface, maxilla and mandible is expected to be largely completed in patients aged 12 years and above, allowing the application of fixation devices. However, it is known that skeletal growth continues up till at least 22 years of age and the use of the subject device should be carefully considered in adolescent patients. Also, medical devices comparable to the subject device are intended to be used in the same patient population (e.g. the predicate device K210731). Therefore, the Subject Device Facial iD System implants may be used safely and effectively in adolescence aged 12 years and above as well as in adult patients.

The Subject Device Facial iD System is a patient-specific implant and ordered on demand, so the scan date should be close to the surgery date. A scan of the patient close to the planned surgery date is requested from the surgeon and then further processed directly after the request has been initiated. Since the entire process takes place within a timely manner, the risks of inadequate fixation and failure of the device due to outdated input data are mitigated.

Radiation exposure is of concern for adult and particularly for adolescent patients. Special considerations included in the labeling to minimize ionizing radiation by using limited radiation dosage when deemed appropriate based on patient condition and clinical needs.

The management of orbital trauma and orbital defects may require a multi-disciplinary approach including multi-disciplinary operative management. This approach includes

different surgeon specialties who are selecting the appropriate patient, who are defining the implant and who are performing the procedure.

VIII. CONCLUSIONS

The results of the performance data demonstrate that the Subject Device Stryker Facial iD System will perform as intended in the specified use conditions. 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 of the Subject Device to the Predicate Device.