March 26, 2020

Stryker
Zainab Amini
Senior Regulatory Affairs Specialist
750 Trade Centre Way- Suite 200
Portage, Michigan 49002

Re: K193143
Trade/Device Name: Stryker Facial iD Plating System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: February 27, 2020
Received: February 28, 2020

Dear Zainab Amini:

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 Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*

K193143

Device Name
Stryker Facial iD Plating System

Indications for Use *(Describe)*

The Stryker Facial iD Plating 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:
-Orthognathic surgery
-Reconstructive maxillofacial surgery
-Mandible and maxillofacial 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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510(k) Summary

I. INTRODUCTION

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

II. SUBMITTER

510(k) Owner:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Zainab Amini Senior Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-8349 Fax: 877-648-7114
Date prepared:	March 26, 2020

III. DEVICE

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

IV. PREDICATE DEVICE

Primary Predicate: K182305, Stryker Facial iD Plating System
Reference Device: K192192, VSP® System

V. SUBJECT DEVICE DESCRIPTION

The Stryker Facial iD Plating System 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 orthognathic surgery, reconstructive maxillofacial surgery, and mandible and maxillofacial trauma surgery.

The Subject Device plate(s) are additively manufactured patient-specific plates, and the patient-specific design of the plates allows certain features to be configured to meet the individual needs of each patient. The Subject Device plate(s) are provided with a Design Proposal, an electronic Instruction for Use (IFU) and an optional Anatomical Model.

INDICATIONS FOR USE

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

	Subject Device, K193143	Primary Predicate Device, K182305
Intended Use/Indication for Use	The Stryker Facial iD Plating 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: - Orthognathic Surgery - Reconstructive maxillofacial surgery - Mandible and maxillofacial trauma surgery	The Stryker Facial iD Plating 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: - Orthognathic surgery - Reconstructive maxillofacial surgery - Mandible and maxillofacial trauma surgery

The Intended Uses and the specific Indication for Use of the Subject Device and Primary Predicate Device are identical.

Reference Device: K192192, VSP® System - Patient specific maxillofacial anatomical models, templates, guides, and surgical plans. This is added for compatibility to the Subject Device. Information regarding this reference device is not necessary for the substantial equivalence comparison.

The purpose of this Special 510(k) submission is due to Stryker's software update, and additionally, to show compatibility of the Subject Device implants with the VSP System cleared in K192192.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY PREDICATE DEVICE

The Subject Device is compared to the Primary 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.

B. Technological Characteristics

The fixation method, material, non-sterility and sterilization method, patient-specific offering and design are identical when comparing the Subject and Primary Predicate Device. Most importantly, performance test data shows the Subject Device is substantial equivalent to the Primary Predicate Device.

The bone plating system of the primary predicate device and the subject device remain identical. This 510(k) includes a software updates and shows compatibility to the VSP System (K192192). Updates include automated bone thickness measurements and visualization, which aids in visualization for plate design and screw hole placement; and plate design process improvements (i.e., naming of files, cosmetic display). Software Verification and Validation testing were performed for the software updates. As shown in the performance testing in the cadaver lab the interaction between the surgical guides and the Facial iD plates are not changing in any way compared to their previous clearance.

1. PERFORMANCE DATA

The following performance testing to show substantial equivalency:

The Subject Device is identical to the Primary Predicate Device for cleaning and sterilization validation. Additionally, biocompatibility testing is not necessary for the Subject Device as there have been no changes in the Subject Device material and process, and therefore the Subject Device is identical to the Primary Predicate Device.

Performance Bench Testing

Performance testing, cleaning and sterilization, shipping and handling done for the Primary Predicate Device in K182305 are valid for the Subject Device. The end-user test validation of the Subject Device in a cadaver lab showed that the subject device is performing as intended in the specified use conditions. Software verification and validation were performed according to internal procedures and IEC 62304. Therefore, the subject device met all pre-defined acceptance criteria as the primary predicate device, and the results of the tests support the substantial equivalence of the subject device to the primary predicate 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.

2. CONCLUSIONS

The results of the performance tests demonstrate that the Subject Device, Stryker Facial iD Plating 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 Primary Predicate Device.