June 28, 2019

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

Re: K190696
Trade/Device Name: Stryker Surgeon iD Mandible Recon Plate
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: May 29, 2019
Received: May 30, 2019

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.
Acting Assistant 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)*
K190696

Device Name
Stryker Surgeon iD Mandible Recon Plate

Indications for Use *(Describe)*
The Stryker Surgeon iD Mandible Recon Plate is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.
The Stryker Surgeon iD Mandible Recon Plate is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction and secondary mandibular reconstruction.

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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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
79111 Freiburg, Germany

Submitter/
Contact Person: Zainab Amini
Regulatory Affairs Specialist
Stryker Craniomaxillofacial
750 Trade Centre Way
Portage, MI 49002
Phone: 269-389-8349
Fax: 877-648-7114

Date prepared: June 28, 2019

II. DEVICE [§807.92(a)(2)]

Trade Name: Stryker Surgeon iD Mandible Recon Plate

Common or
Usual name: Bone Plate

Classification
name: Bone Plate, 21 CFR §872.4760

Regulatory
Class: Class II

Product Code: JEY

III. PREDICATE DEVICE [§807.92(a)(3)]

Predicate: Stryker Customized Mandible Recon Plate Kit – K132519

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

The Subject Device, the Stryker Surgeon iD Mandible Recon Plate is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.

The Surgeon iD Mandible Recon Plate is a surgeon-specific plate which is designed based on an average mandible model. The plate is designed per surgeon's preference within the following design envelope. The Surgeon iD Mandible Recon Plate is offered in hemi and full shapes and three different sizes (Small, Medium, and Large). The plate can be designed with a profile height of 2.0 mm or 2.8 mm, with a number of screw holes between 4 and 50, and bar widths between 5.5 mm and 6.5 mm. The plate is made of commercially pure titanium.

V. REFERENCE DEVICE

K014263, Stryker Universal Mandible System

The Stryker Universal Mandible System is intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction and cleared in K014263. The Reference Device and the Subject Device has similar fixation system and accessories and therefore, serves as the Reference Device for this submission.

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

TABLE 1 SUBJECT AND PREDICATE DEVICE'S INDICATION FOR USE.

	Subject Device: Stryker Surgeon iD Mandible Recon Plate (SMRP)	Predicate Device: Stryker Customized Mandible Recon Plate (CMRP), K132519
Intended Use/ Indication for Use	The Stryker Surgeon iD Mandible Recon Plate is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.	The Customized Mandible Recon Plate Kit is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.
	The Stryker Surgeon iD Mandible Recon Plate is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction and secondary mandibular reconstruction.	The Customized Mandible Recon Plate Kit is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction and secondary mandibular reconstruction.

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

The Subject Device has an identical principle of operation, and technological characteristics as the Predicate Device. However, the Subject Device Surgeon iD Mandible Recon Plate is surgeon-specific, the plates are designed per surgeon's preferences and offered in three sizes (Small, Medium, and Large). The plates may be modified intra-operatively to fit a specific patient's anatomy (e.g., by cutting or bending). The Subject Device Stryker Surgeon iD Mandible Recon Plate is based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The basic operational principle of the Subject and the Predicate Device is rigid internal fixation of primary and secondary mandibular reconstructions.

B. Technological and Operational Characteristics

The technological and operational characteristics of the Subject and the Predicate Device is to reconstruction or bridging of mandible resection, and area of the application is mandible.

VIII. PERFORMANCE DATA [§807.92(b)(1)]

The Subject Device is equivalent to the Predicate Device for cleaning and sterilization validation, the Subject Device's biocompatibility testing and sterilization validations are referenced in the Predicate Device.

Performance Bench Testing

Verification and Validation activities were assessed on the Subject Device Surgeon iD Mandible Recon Plate, the V&V activities are referenced in the Predicate Device and Reference Device. Additionally, the following performance testing were completed for the Subject Device:

- Analysis of Functional Interfaces
- Evaluation of the Models
- Compatibility
- Packaging

The results of the activities showed that the Subject Device met all pre-defined acceptance criteria. Therefore, the Subject Device is substantially equivalent to the Predicate and Reference Devices.

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.

IX. CONCLUSIONS [§807.92(b)(3)]

The results of the non-clinical data demonstrate the Subject Device will perform as intended in the specified use conditions. According to the comparison based on the requirements of 21 CFR 807.92 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.