Stryker Craniomaxillofacial (CMF)
Zainab Amini
Sr. RA Specialist
1941 Stryker Way
Portage, Michigan 49002

12/9/2022

Re: K222650
Trade/Device Name: Stryker Cutomized Mandible Recon Plate; Stryker Surgeon iD Mandible Recon Plate
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: November 8, 2022
Received: November 9, 2022

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,

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.

Submission Number *(if known)*

K222650

Device Name

Stryker Cutomized Mandible Recon Plate; and
Stryker Surgeon iD Mandible Recon Plate

Indications for Use *(Describe)*

CMRP:
The Customized Mandible Recon Plate is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction, secondary mandibular reconstruction, and mandibular fracture fixation.

SMRP:
The Surgeon iD Mandible Recon Plate is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction, secondary mandibular reconstruction, and mandibular fracture fixation.

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 summarizes 510(k) information in accordance with 21 CFR 807.92 requirements.

I. SUBMITTER

510(k) Owner:	Stryker Leibinger GmbH& Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Zainab Amini Staff, Regulatory Affairs Specialist Stryker Craniomaxillofacial 1941 Stryker Way Portage, MI 49002 Phone: 269-290-8072 Fax: 877-648-7114
Date prepared:	December 8th, 2022

II. DEVICE

Trade Name:	Stryker Customized Mandible Recon Plate Stryker Surgeon iD Mandible Recon Plate
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

Primary Predicate Device: K193136, Stryker Customized Mandible Recon Plate Kit

Reference Devices: K190696, Stryker Surgeon iD Mandible Recon Plate

K014263, Stryker NewGen/Universal Mandible System

IV. SUBJECT DEVICE DESCRIPTION

The subject devices include the Stryker Customized Mandible Recon Plate (CMRP) and Stryker Surgeon iD Mandible Recon Plate (SMRP). Both CMRP and SMRP are intended to be used for rigid internal fixation of primary, secondary mandibular reconstructions, and fixation of mandibular fractures; and have an indication for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction, secondary mandibular reconstruction, and mandibular fracture fixation. Subject devices have similar intended use and technical characteristics as the primary predicate device (K193136) and the reference device (K190696), and the additional language in indications for use statement is supported by the reference device (K014263).

The subject devices' plate(s) are designed and manufactured for one patient and/or surgeon specifically, and the customized patient-specific and surgeon-specific design of the plate(s) allows certain features to be configured to meet the individual needs of each patient and surgeon. The subject devices' plate has additional design configuration options (such as branches and flanges, and updated plate bar widths of 5.75-7.5mm) when compared to the primary predicate device. The subject devices' plate(s) are provided with the Design Proposal document, an Instruction for Use (IFU), and an optional Anatomical Model. Additionally, the subject device is compatible with a separately provided Surgical Guides accessory.

V. INDICATIONS FOR USE

Table 1: Comparison of Indication for Use.

	Subject Device, (CMRP), K222650	**Subject Device, (SMRP), K222650**	**Primary Predicate Device, K193136**	**Reference Device, K190696**	**Reference Device, K014263**
Intended Use/ &	The Customized Mandible Recon Plate is intended to be used for rigid internal fixation of primary, secondary mandibular reconstructions, and fixation of mandibular fractures.	The Surgeon iD Mandible Recon Plate is intended to be used for rigid internal fixation of primary, secondary mandibular reconstructions and fixation of mandibular fractures.	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 intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.	The Stryker NewGen/Universal Mandibular System is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fracture and mandibular reconstruction.
Indications for Use	The Customized Mandible Recon Plate is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction, secondary mandibular reconstruction, and mandibular fracture fixation.	The Surgeon iD Mandible Recon Plate is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction, secondary mandibular reconstruction and mandibular fracture fixation.	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.	The Stryker Surgeon iD Mandible Recon Plate is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging untiled secondary reconstruction and secondary mandibular reconstruction.	

The subject device's indication for use statement is similar to the primary predicate device but with the addition of the fracture fixation of the mandible, which is supported by the reference device K014263. The reference device K190696 is also identified for similar reasons as the primary predicate, to support SMRP device. Therefore, substantial equivalence is shown between the subject devices and predicate devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject devices are the Stryker Customized Mandible Recon Plate and Surgeon iD Mandible Recon Plate based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The basic operational principle of the Stryker Customized Mandible Recon Plate and Surgeon iD Mandible Recon Plate is the stabilization, reconstruction, and/or bridging of mandible reconstruction and fracture fixation.

B. Technological Characteristics

The technological characteristics of the subject devices is similar to their previously cleared technological characteristics, but with additional design configuration options (such as branches and flanges, updated plate bar widths (5.75mm-7.5mm), and transition radius (1.6mm)). Stryker Customized and Surgeon iD Mandible Recon Plates is for the reconstruction or bridging of mandible resection, and area of the application is mandible.

Additionally, the subject devices include updated intended use/indications for use to incorporate fracture fixation of mandibles, updated design feature configuration, and updated IFUs (Instruction for Use).

The subject devices' intended use and indications for use is similar to the primary predicate device (K193136) and the reference device (K190696), and the additional language in indications for use statement is supported by the reference device (K014263). Subsequently, the subject devices' IFU has been updated to reflect these changes.

The incorporated design feature configurations contain branches and flanges to increase design flexibility. Branches are normal bars with screw holes that branch off the normal plate line and offer a greater variety to fixate the bone fragments. Flanges are bars that close out without a screw hole at the end of the bar. These flanges branch off the plate to wrap around the bone to increase the plate fit. The new design envelope is presented in Table 1.

Table 1: Design envelope	
Plate Material	Commercially pure titanium (grade 2)
Type of design	Customized
# Of screw holes	4-35 (variable)
Ranges of shapes	Hemi and full, branches, flanges
Screw systems	2.0, 2.3 mm, 2.7mm
Plate profile height	2.0 mm and 2.8 mm
Bar width	5.75 mm – 7.5 mm

VII. PERFORMANCE DATA

The following performance testing was done to show substantial equivalence:

The subject devices' cleaning, and sterilization are same as previously cleared devices as demonstrated within the submission. Therefore, new testing and validation for cleaning, and sterilization are not required to prove substantial equivalency to the predicate device.

The proposed modifications for the subject devices have been assessed and validated to show their safety and effectiveness. The below testing and assessment were done to support substantial equivalence of the subject devices to the predicate device.

- Biocompatibility Assessment according to ISO 10993-1.
- Mechanical strength testing
- End User Validation

Performance Bench Testing

As stated above, mechanical strength testing was performed on the subject device plate(s).

All tests had been performed with the corresponding worst case design for the new design envelope and design features (branches and flanges) subject to this submission. For the biomechanical tests, all new design options incorporated a screw hole to bar connection. The entire mechanical stress concentrated to the screw hole representing the worst case. This was tested in 4-point bending and cantilever bending tests. The tests were performed according to the standards ASTM F382 and ASTM STP 731.

The mechanical strength testing results were included within this submission. The subject devices met all pre-defined acceptance criteria, and the results of the tests support the substantial equivalence of the subject devices to the predicate device.

The End User Validation was performed as a simulated use in a Cadaver Lab, where surgeons performed the surgery in a realistic scenario. Validation by skilled users demonstrated that the user needs / design inputs were met for the subject devices.

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.

VIII. CONCLUSIONS

The results of the performance testing provided in this submission demonstrate the subject devices, Stryker Customized Mandible Recon Plate and Stryker Surgeon iD Mandible Recon Plate, 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.