March 26, 2020

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

Re: K193136
Trade/Device Name: Stryker Customized Mandible Recon Plate Kit
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)*

K193136

Device Name
Stryker Customized Mandible Recon Plate Kit

Indications for Use *(Describe)*
The Customized Mandible Recon Plate Kit is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.

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.

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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K193136

510(k) Summary510(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
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Date prepared: March 26, 2020

III. DEVICE

Trade Name: Stryker Customized Mandible Recon Plate Kit

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: K132519, Stryker Customized Mandible Recon Plate Kit
Reference Device: K192192, VSP® System

V. SUBJECT DEVICE DESCRIPTION

The Subject Device, CMRP Kit (CMRP) is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions and is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction and secondary mandibular reconstruction. The CMRP was cleared in K132519 and serves as an identical cleared Predicate Device, which shows the implant design software and design process, implant compatibility with the anatomical model, and the utilization of customized Guides which are similar to those offered for use with the Subject Device Stryker Customized Mandible Recon Plate Kit.

The Subject Device plate(s) are 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 the Design Proposal, an Instruction for Use (IFU), and an optional Anatomical Model. Additionally, the Subject Device is compatible with a separately provided Guides accessory.

INDICATIONS FOR USE

Table 5- 1: Comparison of Indication For Use.

	Subject Device, K193136	Predicate Device, K132519
Intended Use/ and Indications for Use	The Stryker Customized Mandible Recon Plate Kit is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.	The Stryker Customized Mandible Recon Plate Kit is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.
	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 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 Intended Uses and Indication for Use of both, the Subject and Predicate Devices 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 PREDICATE DEVICE

The Subject Device Stryker Customized Mandible Recon Plate Kit is 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 Kit is the stabilization of mandibular reconstruction.

B. Technological Characteristics

The technological characteristics of Subject Device remain the same as the Predicate Device. Stryker Customized Mandible Recon Plate Kit (CMRP) is for the reconstruction or bridging of mandible resection, and area of the application is mandible.

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. 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 Subject Device plates are not changing in any way compared to their previous clearances.

VII. PERFORMANCE DATA

The following performance testing to show substantial equivalency:

The Subject Device is identical to 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 Predicate Device.

Performance Bench Testing

Performance testing, cleaning and sterilization, shipping and handling done for the Primary Predicate Device in K132519 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.

VIII. CONCLUSIONS

The results of the performance testing demonstrate the Subject Device, Stryker Customized Mandible Recon Plate 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.