Stryker Leibinger GmbH & Co. KG
Amelia Kesti
Staff Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, Freiburg D-79111
GERMANY

11/9/2022

Re: K221855
Trade/Device Name: Universal CMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: October 5, 2022
Received: October 7, 2022

Dear Amelia Kesti:

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)*

K221855

Device Name

Universal CMF System

Indications for Use *(Describe)*

Craniomaxillofacial Implants:
The Universal CMF System is a Craniomaxillofacial (CMF) plate and screw system intended for osteotomy, stabilization and rigid fixation of CMF fractures and reconstruction.

Mandible Implants:
The Universal CMF System (mandible modules) is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and 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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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
D-79111 Freiburg, Germany

Submitter/ Contact Person: Amelia Kesti
Staff Regulatory Affairs Specialist
Stryker Craniomaxillofacial (CMF)
1941 Stryker Way
Portage, MI 49002

Phone: 269-330-5919

Date prepared: 11/09/2022

II. DEVICE [§807.92(a)(2)]

Trade Name:	Universal CMF System
Abbreviated Name:	Universal CMF System
Common or Usual Name:	Bone Plates, Bone Fixation Fasteners
Device:	Universal CMF System
Classification Name & Regulation Description:	Plate, Bone; per 21 CFR §872.4760
Regulation Medical Specialty & Review Panel:	Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, Office of Product Evaluation and Quality (OHT1) / Division of Dental Devices (DHT1B)
Product Code:	JEY
Subsequent Prod. Codes:	
Regulatory Device Class:	Class II

III. PREDICATE DEVICE [§807.92(a)(3)]

A. Predicate Devices: The predicate devices for this bundled, traditional 510(k) are:

1. Universal CMF System - K022185

i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

2. Stryker NewGen/Universal Mandibular System - K014263

i. Submission Branch of Predicate Device- Division of Dental, Infection Control, and General Hospital Devices; Office of Device Evaluation, Center for Devices and Radiological Health

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

A. Submission Branch of Subject Device: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, Office of Product Evaluation and Quality (OHT1) / Division of Dental Devices (DHT1B)

B. Subject Device: Universal CMF System

V. The subject device (combination of Universal CMF System (K022185) and NewGen/Universal Mandibular System (K014263)) consists of multiple modules including fracture and reconstruction modules. The modules consist of straight, angled, hemi/full mandible bridging, curved, and pre-bent plates. The screws in the modules include 1.2-2.7mm self-tapping, self-drilling, and locking screws that vary from 3mm-42mm in length. The plates and screws are made of commercially pure titanium (ASTM F 67-95) and titanium alloy (ASTM F136-98). See Table 1 below for a summary of dimensions for the subject device and predicates. There is no change to the subject device as part of this submission, only labeling changes.

Table 1: Comparison of Size Ranges Between the Predicate And Subject Devices

Dimension range or attribute	Predicate Devices – K022185 and K014263	Subject Device	Explanation of differences
Plate Length (straight and 3D plates only)	Min 9.35 mm Max 168.36 mm	Min 9.35 mm Max 168.36 mm	No differences in comparison
Screw Length	Min 2.7 mm Max 42 mm	Min 2.7 mm Max 42 mm	No differences in comparison
Screw	Min 0.8 mm	Min 0.8 mm	No differences

Diameter	Max 1.9 mm	Max 1.9 mm	in comparison
Plate Profile Height	Min 0.3 mm Max 2.85 mm	Min 0.3 mm Max 2.85 mm	No differences in comparison
Plate Main bar width (not applicable for plates with double strip)	Min 0.65 mm Max 5.5 mm	Min 0.65 mm Max 5.5 mm	No differences in comparison
Plate Outer diameter at screw hole	Min 3 mm Max 9 mm	Min 3 mm Max 9 mm	No differences in comparison

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

Table 2: Comparison of Indications for Use				
	Subject Device	Predicate Device – K022185	Predicate Device – K014263	Equivalence Assessment
Indications for Use	Craniomaxillofacial Implants: The Universal CMF System is a Craniomaxillofacial* (CMF) plate and screw system intended for osteotomy, stabilization and rigid fixation of CMF fractures and reconstruction. Mandible Implants: The Universal CMF System (mandible modules) is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.	The Stryker Leibinger Universal CMF System is a Cranio-maxillofacial (CMF) plate and screw system intended for osteotomy, stabilization and rigid fixation of CMF fractures and reconstruction.	The Stryker Leibinger New Generation System is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.	Similar The K022185 and K014263 indications are kept the same in the new submission. The indications listed in the new submission are the same as the predicates, but are labeled as "Craniomaxillofacial Implants" and "Mandible Implants" for K022185 and K014263 respectively.

*The use of the term "craniomaxillofacial" in the subject device's intended use and indication for use is to maintain alignment with the name of the System. Additionally, the term "craniomaxillofacial" is not intended for cranial use, but rather to address fractures where there is some overlap between the cranial and facial bones. For clinical conditions involving the cranium, Universal Neuro System (K031659) is utilized. This is a separate 510(k) cleared device specifically intended for the cranium and is not part of this K221855 submission.

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

The subject device is compared to its predicate device for substantial equivalence of technological characteristics based on the following criteria:

A. Principles of Operation
B. Technological Characteristics

This submission is intended to demonstrate substantial equivalence for the following proposed changes: changing device name to Universal CMF System, merging indications for use, harmonization to add new sterilization parameters across the subject devices from previous clearances, and labeling changes.

A. Principles of Operation / Operating Principle

The operational principle of the subject device is a plate and screw system intended for stabilization and rigid fixation of the craniomaxillofacial (CMF) skeleton. The method of site preparation, implant preparation, and fixation remains the same as the predicate devices as there is no change to the device.

B. Technological Characteristics

The technological characteristics of the subject device remain the same as the predicates. See table 3 below for a comparison of technological characteristics between the predicate and subject devices:

- Similar Intended Use and Indication for Use: The K022185 and K014263 indications are kept the same. The indications listed in the subject device are the same as the predicates but are labeled as "Craniomaxillofacial Implants" and "Mandible Implants" for K022185 and K014263 respectively.
- Same Mode of Fixation: There is no change to the mode of fixation of subject device as part of this submission, only labeling changes.

- Same Materials of Construction: There is no change to the materials of construction to the subject device as part of this submission, only labeling changes.
- Same Design: There is no change to the design of the subject device as part of this submission. This 510(k) is submitted to demonstrate substantial equivalence for the following proposed changes: changing device name to Universal CMF System, merging indications for use, harmonization to add new sterilization parameters across the subject devices from previous clearances, and labeling changes.

Table 3: Comparison of Technological Characteristics Between the Predicate And Subject Devices

	Predicate Device – K022185	Predicate Device – K014263	Subject Device	Explanation of differences
Mode of fixation	Fixated to bone	Fixated to bone	Fixated to bone	No differences in comparison
Operating Principle	The operating principle of the Universal CMF System is to stabilize or rigidly fixate bone during osteotomy for fractures and reconstruction using plates and screws.	The operating principle of the Universal CMF System is to stabilize or rigidly fixate mandibular fractures during mandibular reconstruction using plates and screws.	The operating principle of the Universal CMF System to stabilize or rigidly fixate craniomaxillofacial (CMF) skeleton for fractures and reconstructive surgeries using plates and screws.	This is only a labeling change, there is no change to the product design or use. The two prior 510(k)s are being combined under one brand- Universal CMF System.
Device materials	Commercially pure titanium (ASTM F 67-95) and titanium alloy (ASTM F136-98)	Commercially pure titanium (ASTM F 67-95) and titanium alloy (ASTM F136-98)	Commercially pure titanium (ASTM F 67-95) and titanium alloy (ASTM F136-98)	No differences in comparison
Device design	The Universal CMF System (K022185) is a comprehensive craniomaxillofacial titanium plating system and includes a wide selection of implants for bone fixation of craniomaxillofacial fractures and reconstruction. The system consists of multiple modules including: 1.2mm Upperface Plating, 1.7mm Midface Plating, Orthognathic Fixation, and 2.0mm Mini Plating Modules. The modules consist of straight, angled, curved, and pre-bent	The NewGen/Universal Mandibular System (K014263) is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular factures and mandibular reconstruction. The system consists of modules including: 2.0mm and 2.3mm Fracture and Reconstruction Modules. The 2.0 and 2.3mm Fracture/Reconstruction Modules consist of straight, angled, curved plates, and pre-bent plates for fractures and hemi/full mandible bridging plates for reconstruction. The screws in the modules include 2.0mm diameter self-tapping,	The subject device (combination of Universal CMF System (K022185) and NewGen/Universal Mandibular System (K014263)) consists of multiple modules including fracture and reconstruction modules. The modules consist of straight, angled, hemi/full mandible bridging, curved, and pre-bent plates. The screws in the modules include 1.2-2.7mm self-tapping, self-drilling, and locking screws that vary from 3mm- 42mm in length. The plates	The subject device is a combination of the two predicate devices (Universal CMF System (K022185) and NewGen/Universal Mandibular System (K014263).

	plates. The screws in the modules include 1.2-2.7mm diameter self-tapping, self-drilling, and locking screws that vary from 3mm-20mm in length. The plates and screws are made of commercially pure titanium (ASTM F 67-95) and titanium alloy (ASTM F136-98).	lag, and locking screws that vary from 4mm-42mm in length. The plates and screws are made of commercially pure titanium (ASTM F 67-95) and titanium alloy (ASTM F136-98).	and screws are made of commercially pure titanium (ASTM F 67-95) and titanium alloy (ASTM F136-98).	
Size ranges	Screws from 0.8mm to 1.9mm in diameter and 2.7mm to 42mm in length. Plates from 9.35mm to 168.36mm in length.	Screws from 0.8mm to 1.9mm in diameter and 2.7mm to 42mm in length. Plates from 9.35mm to 168.36mm in length.	Screws from 0.8mm to 1.9mm in diameter and 2.7mm to 42mm in length. Plates from 9.35mm to 168.36mm in length.	No differences in comparison
Method of sterilization	Provided non-sterile. Sterilized by end user using moist heat (steam) per IFU parameters.	Provided non-sterile. Sterilized by end user using moist heat (steam) per IFU parameters.	Provided non-sterile. Sterilized by end user using moist heat (steam) per IFU parameters.	The sterilization parameters were harmonized for the subject device. The method of sterilization remains the same.

VIII. PERFORMANCE DATA [§807.92(b)(7)]

There are no modifications to the subject device as part of this submission, only labeling changes. The labeling change included a harmonization of the sterilization parameters, testing for this update is outlined below. Table 4 summarizes the sterilization testing performed on the subject device, Table 5 outlines testing conducted under prior clearances (K022185 and K014263) to demonstrate substantial equivalence.

Sterilization and Biocompatibility Testing

The subject device includes single-use medical implants provided non-sterile to the user. Although there were no modifications to the subject device as part of this submission, the sterilization parameters within the IFU (instructions for use) were harmonized. Compared to the predicate devices, the sterilization testing conducted for the subject device has the same sterilization type, source, and validation standards as the predicate devices. Although there is a change in the sterilization parameters listed in the updated IFU for some components of the subject device, the change does not affect the Sterility Assurance Level (SAL) and there is no change to the way the device is provided (device is still provided non-sterile). The change does not affect performance or biocompatibility of the device. The harmonized sterilization parameters for the subject device do not impact sterility of the final end-product, as the harmonization encompasses the previously valid sterilization parameters that were used for the components under prior clearances (K022185 and K014263). A summary of the sterilization testing for the subject device can be found in Table 4 below.

Table 4: Sterilization Testing	
Test	Conclusions
Sterilization Validation (Pre-Vacuum) (DIN EN ISO 14937, DIN EN ISO 17665-1 and ISO/TS 17665-2.)	Pass
Sterilization Validation (Flash Gravity) (DIN EN ISO 14937, DIN EN ISO 17665-1 and ISO/TS 17665-2.)	Pass

Performance Bench Testing

The following testing listed in Table 5 was conducted under the prior clearances (K022185, K014263) to demonstrate substantial equivalence.

Table 5: Testing conducted under the prior clearances (K022185, K014263) to demonstrate substantial equivalence.		
Product	Test	Result
Universal CMF Plates	Biocompatibility (ISO 10993-1)	Pass
Universal CMF Screws	Biocompatibility (ISO 10993-1)	Pass
Universal CMF Screws	Insertion Torque (ASTM F543)	Pass
Universal Mandible and MP System	Removal Torque (ASTM F543)	Pass
Universal CMF Screws	Failure Torque (shaft shear test) (ASTM F543)	Pass
Universal CMF Mid-Face Plates	Failure Strength (ASTM F382)	Pass

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)]

In summary, the subject device is substantially equivalent to its predicate device. The subject device's fundamental scientific technology, technological characteristics, and materials of construction are the same as the predicate devices. The subject device's intended use and indications for use have the same scope, content and meaning as the predicate devices. 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 to the predicate device.