



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Stryker
Gregory Gohl
Senior Regulatory Affairs Specialist
750 Trade Centre Way
Suite 200
Portage, Michigan 49002

July 24, 2017

Re: K171364
Trade/Device Name: MP LeFort I Plates
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: June 23, 2017
Received: June 26, 2017

Dear Gregory Gohl:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mary S. Runner -S

for

Lori Wiggins

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171364

Device Name

MP LeFort I Plates

Indications for Use (Describe)

The Stryker® Leibinger Universal CMF and Universal 2.0 Mini Plating Systems are Craniomaxillofacial (CMF) plate and screw systems intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.

The MP LeFort I Plates as part of the predicate subgroup Universal 2.0 Mini Plating System are implants indicated for osteotomy stabilization and rigid fixation of LeFort I fractures of the maxillofacial skeleton.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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SECTION 5
510(k) Summary

Section 5. 510(k) Summary

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

Clearance Number: K171364

I. SUBMITTER

510(k) Owner: Stryker Leibinger GmbH& Co. KG
Boetzingen Strasse 41
D-79111 Freiburg, Germany

Submitter/ Contact Person: Gregory Gohl
Sr. Regulatory Affairs Specialist
Stryker Craniomaxillofacial (CMF)
750 Trade Centre Way
Portage, MI 49002
Phone: 269-389-4319
Fax: 877-648-7114

Date prepared: May 8, 2017

II. DEVICE [§807.92(a)(2)]

Trade Name: MP LeFort I Plates

Common or Usual name: Plate, bone

Classification name: Bone Plate; 21 CFR 872.4760

Regulatory Class: Class II

Product Code: JEY

*Note the company Stryker or legacy name Stryker Leibinger precedes the product/trade name and predicate device in some documentation.

III. PREDICATE DEVICE [§807.92(a)(3)]

Universal CMF System – K022185

The predicate Universal CMF System, which was cleared in K022185, is intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction. The Universal CMF System consists of an implant module for the respective anatomical and indicated areas with each containing various screw and plate versions and shapes.

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

The LeFort I Plates, which were cleared as part of the overall plate system in K022185, have been modified for use with 2.0 mm screws, more flexible applications, and in-between advancements for stabilizing osteotomies. The proposed modifications to the LeFort I Plates comprise a dimensional design modification for maxillofacial use only. There have been no modifications to the screws, meshes/plates, screwdriver blades, or other accessory devices.

V. INDICATIONS FOR USE

The Stryker® Leibinger Universal CMF and its subgroup Universal 2.0 Mini Plating Systems are cranio-maxillofacial (CMF) plate and screw systems intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.

The MP LeFort I Plates as part of the predicate subgroup Universal 2.0 Mini Plating System are implants indicated for osteotomy, stabilization, and rigid fixation of LeFort I fractures of the maxillofacial skeleton.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified Universal CMF System is compared to its 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 basic operational principle of the Universal CMF System remains the same: The operating principle for the Universal CMF System is to stabilize and provide rigid fixation of fractures and reconstruction.

B. Technological Characteristics

The dimensional modification described in this special 510(k) is to the MP LeFort I Plates in the Universal CMF System. However, these modifications do not alter the technological and operational characteristics of the plates in the Universal CMF System. The technological characteristics remain the same:

- Same operating principle: Fracture and osteotomy fixation of small bones
- Same mechanism of action: The plates consist of two screw hole segments that are in parallel to each other with a defined distance to treat fractures and osteotomies advancing the maxilla
- Same construction materials: The subject MP LeFort I Plates are manufactured out of the same material (Titanium Grade 2, ASTM F67) as the predicate device.
- Compatibility of the modified plates with the previously cleared screws and other accessories from K022185 is identical to previously cleared devices of the 2.0 mm module

VII. STERILIZATION VALIDATION AND SHELF-LIFE

The modified plates will be provided non-sterile like the predicate devices. There has been no change in the material or design of the products that impacts end user reprocessing. The subject device is offered to the end users as part of the predicate Universal CMF System, which includes the modules for storage of the implants and different instruments needed for surgery. Therefore, due to the high number of different components, the complete system needs to be steam sterilized at an extended cycle of 6 minutes at 132°C to ensure a sterility level of SAL 10⁻⁶. As it is common practice within hospitals to sterilize all parts of the Universal CMF System together, the extended cycle is indicated in the Instructions for Use for all of the implants stored in the modules, and, therefore, also for the subject device even if single implants themselves can be steam sterilized within 4 minutes at 132°C as recommended in *Appendix C of the FDA Guidance document for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*.

A sterilization reference predicate was identified and tested in a storage module with a cycle of 4 minutes at 132°C, and the storage module was also part of the sterilization validation of the whole system. During the sterilization analysis it was found the subject devices are covered by the representative sterilization reference predicate that was tested through

Attachment 14.2 Sterilization Validation Report and cleared under K014263. Please see Section 14 for additional details.

VIII. PERFORMANCE DATA

Based on the Risk Analysis performed on the modifications to the MP LeFort I Plates in the Universal CMF System, bench testing was performed in support of the substantial equivalence determination.

Biocompatibility and sterility testing was not required as a basis for substantial equivalence. There is no change in the material, manufacturing process, duration or location of contact, or reprocessing methods.

Performance Bench Testing

The following performance bench tests were completed.

- Analysis of functional interfaces
- Fatigue Test

Overall, the results of the performance bench tests support the proposed substantial equivalence of the subject device.

IX. CONCLUSIONS

The results of the non-clinical data demonstrate that the modified MP LeFort I Plates 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.