3/12/2026

Stryker Leibinger GmbH & Co KG
Stephani Herbert
Senior Staff Regulatory Affairs Specialist
Botzinger Strasse 41
Frieburg, 79111
Germany

Re: K254233
Trade/Device Name: CMF MEDPOR® Customized Implant Kit
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin Prosthesis
Regulatory Class: Class II
Product Code: FWP
Dated: February 9, 2026
Received: February 10, 2026

Dear Stephani Herbert:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Alicia Hemphill -S

Digitally signed by Alicia Hemphill -S
Date: 2026.03.12 21:42:28 -05'00'

Alicia L. Hemphill (Johnson), MS
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254233

Please provide the device trade name(s).

CMF MEDPOR® Customized Implant

Please provide your Indications for Use below.

The CMF MEDPOR® Customized Implant is indicated for the augmentation, and/or restoration of bony and/or soft tissue deformities in post-traumatic, post-surgical, or congenital craniofacial defects, including, but not limited to, the correction and prevention of persistent temporal hollowing (PTH).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

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

1. SUBMITTER [§807.92(a)(1)]

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

Submitter/
Contact Person: Stephani K. Herbert, RAC
Sr. Staff Regulatory Affairs Specialist
Stryker
1941 Stryker Way
Portage, MI 49002
Phone: 269-366-7968

Date prepared: December 2, 2025

2. DEVICE [§807.92(a)(2)]

Trade Name:	CMF MEDPOR® Customized Implant
Abbreviated Name:	MEDPOR® CI
Common or Usual Name:	Customized Implant
Device:	Prosthesis, Chin, Internal; per 21 CFR §878.3550
Classification Name & Regulation Description:	Chin prosthesis; per 21 CFR §878.3550
Regulation Medical Specialty & Review Panel:	General & Plastic Surgery
Product Code:	FWP
Regulatory Device Class:	Class II

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

3. PREDICATE DEVICE [§807.92(a)(3)]

510(k) Number: K254233

Primary Predicate Device: Stryker CMF MEDPOR® Customized Implant Kit (also referred to as MEDPOR® CI or MEDPOR® CI Kit) – K191916

Reference Device: PEEK Customized Cranial Implant (CCI) Kit – K203055

The predicate and reference device have not been subject to a device recall.

4. DEVICE DESCRIPTION [§807.92(a)(4)]

The CMF MEDPOR® Customized Implant is a patient-specific implant designed at the request of a surgeon. It is comprised of two identical sterile Implants, an optional Host Bone Model, and a Design Proposal. The implants are individually sterilized using ethylene oxide. The customized implants are molded from porous high-density polyethylene (HDPE) to the specific reconstructed boundaries indicated by the surgeon via submission of CT scans and a customized implant request. This submission expands available design options without altering material composition or intended use.

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

The CMF MEDPOR® Customized Implant is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in post-traumatic, post-surgical, or congenital craniofacial defects, including, but not limited to, the correction and prevention of persistent temporal hollowing (PTH).

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

The subject device has been compared to its predicate devices to demonstrate substantial equivalence in technological characteristics, including principles of operation, material composition and manufacturing processes.

A. Principles of Operation
B. Technological Characteristics

A. Principles of Operation

The basic operational principle of MEDPOR® CI remains the same as the primary predicate. The MEDPOR® CIs are intended to be used to fill bony voids, defects, and contour irregularities in non-load bearing regions of the craniofacial skeleton.

B. Technological Characteristics

Both the Subject and primary predicate devices have the same technological characteristics, principles of operation, design specification and manufacturing processes.

7. PERFORMANCE DATA [§807.92(b)(7)]

Performance data were generated to support the substantial equivalence of the subject device to its predicate devices. The data include non-clinical testing and design validation to demonstrate substantial equivalence. Testing addressed compatibility with optional design features and compatibility with surgical guides, Stryker customized plates, and navigation systems. No changes were made to the device's material composition, intended use, or fundamental design, and therefore previously established performance characteristics remain applicable.

Biocompatibility and Sterility Testing
Biocompatibility and sterility testing were not repeated because the Subject Device uses identical materials, manufacturing processes, and sterilization methods as the primary predicate device.

Performance Bench Testing
Both the subject and predicate devices are designed similarly and manufactured identically. The performance bench testing of the predicate device is valid for the subject device. Additionally, an end-user validation lab was conducted to evaluate the subject device and to support the basis for substantial equivalence.

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.

8. CONCLUSIONS [§807.92(b)(3)]

In summary, the CMF MEDPOR® Customized Implant is substantially equivalent to its 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.