December 12, 2024

CMF Medicon Surgical Inc.
Matthias Alber
Executive Vice President
11200 St. Johns Industrial Pkwy N. Ste. 1
Jacksonville, Florida 32246

Re: K241253
Trade/Device Name: Medicon Epiplating System
Regulation Number: 21 CFR 878.3680
Regulation Name: Nose Prosthesis
Regulatory Class: Class II
Product Code: FZE
Dated: May 3, 2024
Received: September 13, 2024

Dear Matthias Alber:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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: 2024.12.12 17:53:26 -06'00'

Alicia L. Hemphill
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241253

Device Name

Medicon Epiplating System

Indications for Use *(Describe)*

The Medicon Epiplating System is indicated for the attachment of an external restoration prosthesis for restoration of a physical defect when other means of attachment are inadequate. The Epiplating system provides the bone anchorage for the prosthetic attachment. These devices are indicated for use in the maxillo-craniofacial region (including ear, nose and eye).

Type of Use *(Select one* or *both,* as *applicable)*

IZI Prescription Use (Part 21 CFR 801 Subpart D) 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

Submitter's Name and Address: CMF MEDICON SURGICAL INC
11200 St. Johns Industrial Pkwy N. Suite 1
Jacksonville, FL 32246
USA

Official Contact: Matthias Alber
Executive Vice President

Contact Person and Telephone: Matthias Alber
904-642-7500

Date Summary Prepared: 11/19/2024

Device Name: Proprietary Name – Medicon Epiplating System

Device Class: Class II

Classification: 21 CFR § 878.3680

Product Code: FZE

Predicate Device:
Primary Predicate Device

Manufacturer	Device Name	K Number	Classification
Southern Implants (Pty) Ltd.	Osseointegrated Fixtures	K161548	Prosthesis, Nose, Internal

Reference Devices

Manufacturer	Device Name	K Number	Regulation number and product code	Classification
MEDICON, E.G.	TITANIUM MINIPLATE SYSTEM	K951690	872.4760 JEY	Plate, Bone
MEDICON, E.G.	CMS CRANIO MAXILLO FACIAL TITANIUM IMPLANT SYSTEM	K951691	872.4760 JEY	Plate, Bone
HOWMEDICA LEIBINGER, INC.	Epitec™ Titanium Implant System	K961719	888.3030 HRS	Plate, Fixation, Bone

Device Description:
The Medicon Epiplating System is an implant system consisting of various plates used as the foundation for anchoring prostheses or epitheses in the craniofacial region. The system offers various implant sizes to fit the anatomical needs of a wide variety of patients. Components are manufactured from pure titanium (ASTM F67) or Ti6Al4V alloy (ASTM F136).

Indication for Use:
The Medicon Epiplating System is indicated for the attachment of an external restoration prosthesis for restoration of a physical defect when other means of attachment are inadequate. The Epiplating system provides the bone anchorage for the prosthetic attachment. These devices are indicated for use in the maxillo-craniofacial region (including ear, nose and eye).

Technological Characteristics:
The subject Medicon Epiplating System and the predicate devices are all used in the same way: they are fixated in bone where they are intended to osseointegrate to provide an attachment for a prosthesis. The material for all implants and the operating principle, which is permanent fixation by osseointegration, are the same.

The subject and predicate devices are based on the following same technological elements:

	Subject Device K241253	**Predicate Device K161548**	**Reference Device K961719**
Trade name:	Medicon Epiplating System	Osseointegrated Fixtures	EPITEC TITANIUM IMPLANT SYSTEM
Indications for use:	The Medicon Epiplating System is indicated for the attachment of an external restoration prosthesis for restoration of a physical defect when other means of attachment are inadequate. The Epiplating system provides the bone anchorage for the prosthetic attachment. These devices are indicated for use in the maxillo-craniofacial region (including ear, nose and eye).	Southern Implants Osseointegrated Fixtures is indicated for the attachment of an external aesthetic restoration prosthesis for the restoration of a physical defect when other means of attachment are inadequate. The endosseous implant provides the bone anchorage for the prosthetic attachment. These devices are indicated for use in the maxillo-craniofacial region (including ear, nose and eye).	The Epitec system can be used for the fixation of diverse kinds of craniofacial prostheses, including the following examples: Ear prostheses Orbital prostheses Nose prostheses Cheek prostheses Hair pieces Although the Epitec system will primarily be used for the alloplastic reconstruction of craniofacial defects caused by genetic anomalies, tumor resections, or trauma, it can also be used in other craniofacial cases best treated with surgical anchoring.
User Interface	Manual insertion of the implants with specifically developed tools provided to the end-user. In addition, instructions for use are available.	Same	Same
Operating Principle	Permanent fixation by osseointegration	Same	Same
Physical (Design)	Plates and screws in many different shapes	Single implants with different lengths and diameters	Plates and screws in many different shapes
Bone fixation points per implant	Multiple	Single	Multiple
Materials	Titanium	Same	Same
Sterility	Unsterile delivery	Sterile delivery	Unsterile Delivery
Biocompati	ASTM F136-13	Same	Same

	Subject Device K241253	Predicate Device K161548	Reference Device K961719
bility	ASTM F67-13 ISO 5832-2 ISO 5832-3		
Cleaning and Sterilization	Pre-vacuum (steam) sterilization in accordance with ANSI/AAMI/ISO 17665-1:2006/(R)2013 Manual cleaning and machine cleaning in accordance with AAMI TIR30:2011	Not applicable, items are delivered in sterile condition	Unknown

As was established in this submission, the subject Medicon Epiplating System is substantially equivalent to the other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent based on technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function.

Performance Data:
The following performance data were provided in support of the substantial equivalence determination:

Mechanical testing
Bench testing of the Medicon Epiplating System was performed in accordance with ASTM F382. The following tests were performed with the worst-case implant:
- proof of load,
- bending strength,
- bending stiffness (=slope)
- structural bending stiffness of the worst-case implant

A side-by-side comparison and detailed worst-case analysis of each of the subject devices to the reference device K961719 has been performed. K961719 has the same indications for use and a very similar design as this subject device. The results of this side-by-side comparison demonstrate substantial equivalence to the legally marketed predicate devices.

Sterilization validation
Pre-vacuum (steam) sterilization in accordance with ANSI/AAMI/ISO 17665-1:2006/(R)2013.

Cleaning
Manual cleaning and machine cleaning validation in accordance with AAMI TIR30:2011.

Biocompatibility
Previously cleared devices with identical material and manufacturing methods have been tested according to ISO 10993-1.

Conclusion:
Based on the indication for use, technological characteristics, mechanical testing, and comparison to predicate devices, the subject Medicon Epiplating System demonstrates substantial equivalence to the legally marketed predicate devices.