December 19, 2025

Southern Medical (Pty) Ltd.
% Nathan Wright
Engineer & Regulatory Specialist
Applied Technical Services (Empirical Technologies)
4628 NorthPark Drive
Colorado Springs, Colorado 80918

Re: K253373
Trade/Device Name: Southern Maxillofacial (MF) System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: September 29, 2025
Received: September 30, 2025

Dear Nathan Wright:

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,

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K253373

Device Name
Southern Maxillofacial (MF) System

Indications for Use *(Describe)*
The Southern MF System is a maxillofacial plate and screw system intended for osteotomy, reconstruction, and fracture fixation in midface, maxillofacial, and mandibular surgeries.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K253373 – 510(K) SUMMARY

| | |
|---|---|
| Submitter's Name: | Southern Medical (Pty) Ltd |
| Submitter's Address: | 55 Regency Drive<br>Route 21 Corporate Park<br>Irene, Centurion South Africa 0062 |
| Submitter's Telephone: | 27-12-667-6243 |
| Contact Person: | Nathan Wright, MS, RAC<br>Applied Technical Services (Empirical Technologies)<br>1-719-351-0248<br>nawright@atslab.com |
| Date Summary was Prepared: | December 19, 2025 |
| Trade or Proprietary Name: | Southern Maxillofacial (MF) System |
| Device Classification Name: | Plate, Bone |
| Classification & Regulation #: | Class II per 21 CFR §872.4760 |
| Product Code: | JEY |
| Secondary Classification | Class II per 21 CFR §872.4880 |
| Secondary Product Code | DZL |
| Classification Panel: | Division of Dental and ENT Devices |

## DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Southern MF System includes a series of plates, meshes, and screws intended to stabilize and immobilize bone segments in the maxillofacial, midface, and mandibular regions, thereby facilitating osseous fusion in a set orientation. The Southern MF System consists of bone plates made from Grade 2 commercially pure titanium (ASTM F67) in various shapes and sizes to accommodate various surgical requirements. It also includes bone screws made from Ti-6Al-4V ELI (ASTM F136) Titanium Alloy. The bone screws are made available in a variety of lengths and diameters, and in self-drilling and self-tapping variations. The Subject Device is not intended for use in the orbital roof and can only be used if no exposure of the intracranial compartment is presented.

## INDICATIONS FOR USE

The Southern MF System is a maxillofacial plate and screw system intended for osteotomy, reconstruction, and fracture fixation in midface, maxillofacial, and mandibular surgeries.

## TECHNOLOGICAL CHARACTERISTICS

**Predicate Devices**

| 510k Number | Trade or Proprietary or Model Name | Manufacturer | Product Code | Predicate Type |
|---|---|---|---|---|
| K140037 | Optimus CMF System | Osteonic Co., Ltd | JEY, DZL | Primary |
| K160363 | Optimus CMF System | Osteonic Co., Ltd. | JEY, DZL | Reference |
| K953385 | Lorenz 1.0mm, 1.5mm, and 2.0mm System | Walter Lorenz Surgical, Inc. | JEY | Reference |

The subject and predicate devices have the same technological characteristics and the minor differences do not raise any new issues to substantial equivalence. Below is the comparison of the subject device to predicates.

**Predicate Comparison**

| | **Southern Medical Pty, Ltd. Southern Maxillofacial (MF) System (Subject)** | **Osteonic Co., Ltd. Optimus CMF System** | | **Walter Lorenz Surgical (acquired by Biomet) LORENZ 1.0mm, 1.5mm, 2.0mm System (K953385)** | **Comparison** |
|---|---|---|---|---|---|
| | | **(K140037)** | **(K160363)** | | |
| **Regulation** | 872.4760, 872.4880 | 872.4760, 872.4880 | | 872.4760 | Same. |
| **Product Code** | JEY, DZL | JEY, DZL | | JEY | Same. |
| **Indications for Use** | The Southern MF System is a maxillofacial plate and screw system intended for osteotomy, reconstruction, and fracture fixation in midface, maxillofacial, and mandibular surgeries. | Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including:<br>1. Fractures<br>2. Osteotomies<br>3. Reconstructive procedures<br>4. Revision procedures where other treatments or devices have failed. | | The 1.5mm Lorenz System is indicated for trauma, neurosurgery, craniomaxillary reconstruction, and orthognathic procedures in midface. The 2.0mm Lorenz System is indicated for orthognathic surgery of the midface and mandible, oral and maxillofacial trauma, and reconstructive surgery. | Equivalent. The subject specifies the midface application which falls within the maxillofacial application of the predicate indications for use. |
| **Material** | Plates – Unalloyed Titanium (ASTM F67)<br>Screws – Ti-6Al-4V ELI Titanium Alloy (ASTM F136) | Plates – Unalloyed Titanium (ASTM F67)<br>Screws – Ti-6Al-4V ELI Titanium Alloy (ASTM F136) | | Titanium | Same. |
| **Surface** | Anodized (Plates and Screws) | Anodized (Plates only) | | Unknown | Equivalent. Anodization of subject screws raises no questions for substantial equivalence. |
| **Sterility** | Non-sterile | Non-sterile | | Unknown | Same. |
| **Plate Styles and Sizes** | **Styles:** Straight Plates/Dog Bone Plates, Curved Plates, L-Plates, Square & Matrix Plates, X-Plates, T-Plates/Y-Plates, Z-Plates, Chin Plates, LeFort Plates, Angled Plates, H-Plates, Orbital Floor Plates, Meshes, Burr-Hole Plates<br><br>**Thickness (mm)**: 0.2, 0.3, 0.6, 0.8, 1, 1.5 | **Styles:** Straight Plates/Dog Bone Plates, Curved Plates, L-Plates, Square & Matrix Plates, X-Plates, T-Plates/Y-Plates, Z-Plates, Chin Plates, LeFort Plates, Angled Plates, H-Plates, Orbital Floor Plates, Additional Plate Options<br><br>**Thickness (mm)**: 0.6, 0.8, 1., 1.5, 0.4, 0.5, 0.7, 0.8, 1, 1.5, 2, 2.6 | | **Styles:** Straight Plates/Dog Bone Plates, Curved Plates, L-Plates, Square & Matrix Plates, X-Plates, T-Plates/Y-Plates, Z-Plates, Chin Plates, LeFort Plates, Angled Plates, H-Plates, Orbital Floor Plates, Meshes, Burr-Hole Plates, Additional Plate Options<br><br>**Thickness (mm)**: 0.2, 0.3, 0.5, 0.6, 1 | Equivalent. Subject styles and sizes are the same or very similar to those of the predicate. Any minor differences do not impact device performance as compared to the predicate devices; performance testing demonstrates that the Southern CMF System is substantially equivalent to the predicate devices.<br><br>The predicates includes plate styles not offered in the subject system which are not relevant to the comparison for substantial equivalence. |
| **Bone Screws** | **Diameter (mm)**: Ø1.5, Ø1.8, Ø2.0, Ø2.3<br>**Length (mm):** 4 to 16<br>**Style:** Self-Tapping or Self-Drilling | **Diameter (mm)**: Ø1.3, Ø1.5, Ø1.8, Ø1.95, Ø2.0, Ø2.3, Ø2.4, Ø2.7<br>**Length (mm):** 3 to 20<br>**Style:** Self-Tapping, Self-Drilling, Emergency, or IMF | | **Diameter (mm)**: Ø1.5, Ø1.8, Ø2.0, Ø2.3<br>**Length (mm):** 2.5 to 19<br>**Style:** Self-Drilling, Emergency | Equivalent. Subject screw styles are the same as the predicate, and the subject sizes fall within the envelope of predicate screw sizes. The predicates includes screw styles not offered in the subject system which are not relevant to the comparison for substantial equivalence. |

## PERFORMANCE DATA

The Southern Maxillofacial (MF) System has been tested in the following test modes:

- Bone Plate Static and Dynamic Four-Point Bending per ASTM F382
- Screw Axial Pullout per ASTM F543
- Screw Torsional Breaking Force per ASTM F543
- Screw Insertion Torque per ASTM F543

The results of these non-clinical tests show that the strength of the Southern Maxillofacial (MF) System is sufficient for its intended use and the mechanical performance is substantially equivalent to legally marketed predicate devices.

## CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Southern Maxillofacial (MF) System is substantially equivalent to the predicate device.