June 26, 2024

Forma Medical, Inc.
% Jennifer Palinchik
President
JALEX Medical, LLC
27865 Clemens Rd., Suite 3
Westlake, Ohio 44145

Re: K234059
Trade/Device Name: Forma Medical Optimal Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 21, 2024
Received: June 21, 2024

Dear Jennifer Palinchik:

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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K234059

Device Name

Forma Medical Optimal Plating System

Indications for Use *(Describe)*

The Forma Medical Optimal Plating System is intended for fixation of fractures, osteotomies, arthrodeses, and bone reconstructions in adult patients with normal or osteopenic bone. Indications include flat (scapula), long (clavicle, upper and lower extremities including metacarpals, metatarsals, and phalanges), irregular (pelvis, hand, foot) bones and joints (wrist, ankle). The Forma Medical Optimal Plating System is not indicated for ribs, sternum, spine, or the skull.

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."

510(k) Summary

Submitted By:	Forma Medical, Inc. 3401 Hartzdale Drive Suite 103B, Unit #611 Camp Hill, PA 17011
Date:	06/21/2024
Contact Person:	Jennifer Palinchik, President, JALEX Medical
Contact Telephone:	(440) 935-3282
Contact Fax:	(440) 933-7839
Device Trade Name:	Forma Medical Optimal Plating System
Common Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Device Classification Name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	HRS, HWC
Primary Predicate Device:	Globus Medical ANTHEM® Fracture System (K180554)
Reference Device:	Nova Step Airlock® (K151277, K143523) APTUS Foot System (K142581)

Device Description:

The Forma Medical Optimal Plating System is designed to hold bones in relative stability for fracture fixation and arthrodesis. The plates and screws are available in multiple sizes based on patient anatomy and clinical application. The screws are manufactured from titanium, titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F67, F136, F1537, and F138. The plates are manufactured from titanium, titanium alloy, or stainless steel, as specified in ASTM F67, F136, and F138. The system includes plates, screws and instruments. The system instrumentation is manufactured from stainless steel, aluminum, and other surgical grade materials.

Indications for Use:

The Forma Medical Optimal Plating System is intended for fixation of fractures, osteotomies, arthrodeses, and bone reconstructions in adult patients with normal or osteopenic bone. Indications include flat (scapula), long (clavicle, upper and lower extremities including metacarpals, metatarsals, and phalanges), irregular (pelvis, hand, foot) bones and joints (wrist, ankle). The Forma Medical Optimal Plating System is not indicated for ribs, sternum, spine, or the skull.
.

Summary of Technological Characteristics:

The Forma Optimal Plating System and the predicates have the same intended use and fundamental scientific technology. All devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

Item	Forma Medical Optimal Plating System	Globus Medical ANTHEM® Fracture System (K180554)	Nova Step Airlock® (K151277, K143523)	APTUS Foot System (K142581)	Comparison
Classification Name	Single/multiple component metallic bone fixation appliance and accessories Smooth or threaded metallic bone fixation fastener	Single/multiple component metallic bone fixation appliance and accessories Smooth or threaded metallic bone fixation fastener	Single/multiple component metallic bone fixation appliance and accessories	Single/multiple component metallic bone fixation appliance and accessories	Equivalent
Regulation	888.3030, 888.3040	888.3030, 888.3040	888.3030	888.3030	Equivalent
Product Code	HRS, HWC	HRS, HWC	HRS	HRS, HWC	Equivalent
Indications for Use	The Forma Medical Optimal Plating System is intended for fixation of fractures, osteotomies, arthrodeses, and bone reconstructions in adult patients with normal or osteopenic bone. Indications include flat (scapula), long (clavicle, upper and lower extremities including metacarpals, metatarsals, and phalanges), irregular (pelvis, hand, foot) bones and joints (wrist, ankle). The Forma Medical Optimal Plating System is not indicated for	The ANTHEM® Fracture System is indicated for fixation of fractures, osteotomies, arthrodesis and reconstruction of bones for the appropriate size of the device to be used in adult patients, including the clavicle, scapula, humerus, radius, ulna, small bones (metacarpals, metatarsals, phalanges), wrist, pelvis, femur, tibia, fibula, ankle, and foot. The clavicle hook plate may be used for dislocations of the acromioclavicular joint. Mini fragment plates are also	The Airlock® osteosynthesis plate systems are indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusions and reconstruction of small bones of the hands, feet, wrists and ankles, fingers and toes. The system may be used in both adult and pediatric patients.	The APTUS® Foot System is intended for use in small bones, in particular in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.	Equivalent to primary predicate

	ribs, sternum, spine, or the skull.	indicated for fixation of fractures of the acetabulum, patella, and bone fragments, replantation, malunions and nonunions, and for non-load bearing stabilization and reduction of long bone fragments. Small fragment, mini fragment, proximal tibia, clavicle and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius and mini fragment plates may be used in adolescents (12-21 years of age). Plating may be used in patients with osteopenic bone.			
Description	The Forma Optimal Plating System comprises a range of plates and screws created for internal bone fixation. These implants come in a range of sizes and shapes to suit individual patient anatomy and can be either contoured or straight, featuring both locking and non-locking screws. Optimal implants are crafted from materials including titanium, titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as outlined in ASTM standards F67, F136, F1295, F1472, F1537, F2229, F138, and F139. All implants are designed for single-use only.	The ANTHEM® Fracture System is a family of plates and screws designed to be used for internal bone fixation. The implants are available in various sizes and shapes to accommodate patient anatomy, and may be contoured or straight, with locking and non-locking screws. ANTHEM® implants are manufactured from titanium, titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F67, F136, F1295, F1472, F1537, F2229, F138 and F139. All implants are for single use only.	Airlock® osteosynthesis plate systems are are single-use bone fixation devices intended to be permanently implanted. Plates are designed with different shapes and are made of Titanium (Alloy Ti-6Al-4V ELI). The system uses either 3mm or 3,5mm locking and non-locking screws. The drill hole are aligned to make sure there-is no risk of conflict between the screws. The plates vary essentially through different curvatures, lengths, number of holes and shape.	The subject device plates are provided in a variety of anatomical designs, in various lengths, widths and thicknesses. The plate thickness varies from 1.6 mm to 2.0 mm depending on the design. The screw holes of the subject device plates are designed to accommodate appropriately sized subject device screws, or screws presently marketed as part of the APTUS System and previously cleared under K091479. The subject device plates also are compatible with K-wires cleared under K092038. The subject device plates are used with TriLock locking screws and cortical	Equivalent to primary predicate

				(nonlocking) screws. All subject device screws are self-tapping and self-drilling and provided in diameters of 2.0, 2.8 and 3.5 mm, and in various lengths from 8 to 45 mm. The subject device plates are made of commercially pure titanium, Grade 4, conforming to ASTM F67 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700). The subject device screws are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).	
Material	Titanium Alloy, Cobalt Chromium Molybdenum Alloy, and Stainless steel per ASTM F67, F136, F1295, F1472, F1537, F2229, F138 and F139.	Titanium Alloy, Cobalt Chromium Molybdenum Alloy, and Stainless steel per ASTM F67, F136, F1295, F1472, F1537, F2229, F138 and F139.	Titanium (Alloy Ti-6Al-4V ELI).	Titanium Alloy per ASTM F67, ASTM F136	Equivalent to primary predicate
Plate Styles	Straight, Contourable, and pre-shaped	Straight, Contourable, and pre-shaped	Straight, Contourable, and pre-shaped	Straight, Contourable, and pre-shaped	Equivalent to primary predicate
Plate Lengths	23 to 153mm	21mm to 155mm	22.5mm to 53mm	16 to 76 mm	Equivalent
Screw Styles	Locking and Non-locking	Locking and Non-locking	Locking and Non-locking	Locking and Non-locking	Equivalent

Screw Lengths	6mm to 85mm	6mm to 85mm	N/A	8 to 45 mm	Equivalent

Mechanical Testing:

Substantial equivalence is supported by mechanical evaluation to confirm features, geometry, and performance of the subject devices compared to the predicate devices in torsional strength and insertion/removal torque per ASTM F543, and pullout strength per the Chapman analytical formula, as well as four-point bending per ASTM F382.

	Subject Device
	Forma Medical Optimal Plating System
Screw: Torsional Strength per ASTM F543-23	Mechanical testing results demonstrated substantial equivalence to predicate system screws
Screw: Insertion/Removal Torque per ASTM F543-23	Mechanical testing results demonstrated substantial equivalence to predicate system screws
Screw: Pullout Strength	Mechanical testing results demonstrated substantial equivalence per the Chapman analytical formula
Plate: Four-Point Bending per ASTM F382-17	Mechanical testing results demonstrated substantial equivalence to predicate system plates

Conclusion:

Based on the indications for use, technological characteristics, and mechanical testing comparison with the predicate devices, the subject device has demonstrated substantial equivalence.