September 8, 2025

MAXXOS Medical GmbH
Mark Schenk
FDA US Agent
Kirchbühlstraße 6
Mahlstetten, 78601
Germany

Re: K251892
Trade/Device Name: MAXXOS P.A.C.E. Foot & Ankle 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 20, 2025
Received: June 20, 2025

Dear Mark Schenk:

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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

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.	K251892

Please provide the device trade name(s).

MAXXOS P.A.C.E. Foot & Ankle Plating System

Please provide your Indications for Use below.

I. Forefoot System:
The MAXXOS -Forefoot Plating System is “Indicated for Use” in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient.
The Forefoot System is not for Spinal Use.

II. Mid/Hindfoot System:
The MAXXOS - Mid/Hindfoot Plating System is “Indicated for Use” in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of medium/large bones, revision surgeries and replantations in an adult patient. The Mid/Hindfoot System is not for Spinal Use.

III. Ankle Fracture and Fusion System:
The MAXXOS – Ankle Fracture and Fusion System is ”Indicated for Use” in:
1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
2). In intra- and extra articular fractures, osteotomies, medial malleolar fractures and non-unions of the mataphyseal and diaphyseal region of the distal fibula;
3). Fusion of the ankle.
4). In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tiba and fibula in the ankle.
The Ankle Fracture and Fusion System is not for Spinal Use.

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

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

510(k) #: K251892

510(k) Summary

Prepared on: 2025-08-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MAXXOS Medical GmbH
Applicant Address	Kirchbühlstraße 6 Mahlstetten 78601 Germany
Applicant Contact Telephone	610-507-8255
Applicant Contact	Mr. Mark Schenk
Applicant Contact Email	mfschenk@lokconsulting.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	MAXXOS P.A.C.E. Foot & Ankle Plating System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K162674	BioPro Foot Plating Systems	HRS

Device Description Summary

21 CFR 807.92(a)(4)

MAXXOS P.A.C.E. Foot & Ankle Plating System consists of Predicate Foot and Ankle Bone Plate and Locking Screw implant components found with many companies with orthopedic markets in the United States. These 'Bone Plate Systems' fracture fixation implant devices consist of the following catagories:
1. Forefoot Bone Plate System
2. Mid / Hindfoot Bone Plate System
3. Ankle Fracture and Fusion System

A brief and concise description of each system is as follows:

1. The MAXXOS Forefoot Bone Plate System is designed to address a variety of indications in forefoot reconstruction fixation surgery. The system is composed of many locking plate types which include:
1). Straight Fracture Plates, 2). T-Shaped Fracture Plates, 3). Y-Shape Fracture Plates, 4). L-Shaped Fracture Plates, 5). Cloverleaf Fracture Plates, 6). TMT I Medial Fusion Plates, 7). Open Wedge Fusion Plates, 8). MTP Fusion Plates, 9). MTP Fusion Revision Plates, and 10). Dorsal TMT 1 Step Fusion Plates, - in various plate lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 2.0mm, 2.8mm, 3.0mm and 3.5mm sizes in various lengths.

All plates are composed of Ti-6Al-4V ELI (ASTM F136) or CP Ti with an Anodized Type II surface treatment. All screws are composed of Ti-6Al-4V ELI (ASTM F136) with color anodized for sizing.

A full set of Ancillary Instrumentation (Depth Gauges, Drill Guides, Drill Bits, Reamers, Screwdrivers, Retractors, and Bending Irons) is available with the system, but are not specific to the system.

The MAXXOS Forefoot Bone Plate System is offered both EO 'Sterile' and 'Non-sterile' for single-use.

2. The MAXXOS Mid/Hindfoot Bone Plate System is designed to address a variety of indications in midfoot & hindfoot reconstruction fixation surgery. The system is composed of many locking plate types which include: 1). Straight Fracture/Fusion Plates, 2). T-Shaped Fracture/Fusion Plates, 3). L-Shaped Fracture/Fusion Plates, 4). Cloverleaf Fracture/ Fusion Plates, 5). X-Shaped Fracture/Fusion Plates, 6). Retangular Fracture/Fusion Plates, 7). Cotton Osteotomy Plates, 8). Dwyer Step Plates, 9). Evans Osteotomy Plates, 10). Distal Medial & 3/4 Column Plates and 11). ORIF Calcaneal Plates – in various plate lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 3.0mm, 3.5mm and 4.0mm sizes in various lengths.

All plates are composed of Ti-6Al-4V ELI (ASTM F136) or CP Ti with an Anodized Type II surface treatment. All screws are composed of Ti-6Al-4V ELI (ASTM F136) with color anodized for sizing.

A full set of Ancillary Instrumentation (Depth Gauges, Drill Guides, Drill Bits, Reamers, Screwdrivers, Retractors, and Bending Irons) is available with the system, but are not specific to the system.

The MAXXOS Mid/Hindfoot Bone Plate System is offered both EO 'Sterile' and 'Non-sterile' for single-use.

3. The MAXXOS Ankle Fracture and Fusion System is designed to address a variety of indications in ankle reconstruction distal tibia/ fibula fixation surgery. The system is composed of many locking plate types which include:

1). Distal Fibula Plates, 2). Medial Distal Tibia Plates, 3). AnteroLateral Distal Tibia Plates, 4). Posterior Distal Tibia T-Plates, 5). Straight Low Contact Plates, and 6). Straight 1/3 Tubular Plates – in various plate lengths, Right & Left versions, 7) Tibia Fusion Plates– in various plate lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 3.0mm, 3.5mm and 4.0mm sizes in various lengths.

All plates are composed of Ti-6Al-4V ELI (ASTM F136) or CP Ti with an Anodized Type II surface treatment. All screws are composed of Ti-6Al-4V ELI (ASTM F136) with color anodized for sizing.

A full set of Ancillary Instrumentation (Depth Gauges, Drill Guides, Drill Bits, Reamers, Screwdrivers, Retractors, and Bending Irons) is available with the system, but are not specific to the system.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

I. Forefoot System:
The MAXXOS -Forefoot Plating System is "Indicated for Use" in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient.
The Forefoot System is not for Spinal Use.

II. Mid/Hindfoot System:
The MAXXOS - Mid/Hindfoot Plating System is "Indicated for Use" in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of medium/large bones, revision surgeries and replantations in an adult patient.
The Mid/Hindfoot System is not for Spinal Use.

III. Ankle Fracture and Fusion System:
The MAXXOS – Ankle Fracture and Fusion System is "Indicated for Use" in:
1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
2). In intra- and extra articular fractures, osteotomies, medial malleolar fractures and non-unions of the mataphyseal and diaphyseal region of the distal fibula;
3). Fusion of the ankle.
4). In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle.
The Ankle Fracture and Fusion System is not for Spinal Use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use are almost identical to the predicate but differ because they contain "ankle fusion". To support this change, additional plates that were added with justification.

Technological Comparison

21 CFR 807.92(a)(6)

The MAXXOS Medical Foot Plating System and its predicate devices have the same indications for use; same design; are made of identical materials, identical application, and have the same anatomic mechanical properties. Additional plates have been added with engineering justification.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

4 Point Bending Static and Dynamic (ASTM F382-17)
Cantilever Construct Testing Static and Fatigue (ASTM F382-17)
MRI testing as listed below was performed. Results from the test are included in the Instructions for Use.
1. Magnetically induced displacement force (ASTM F2052).
2. Magnetically induced torque (ASTM F2213).
3. MR image artifact (ASTM F2119).
4. Radio frequency induced heating (ASTM F2182).

N/A

Test results, and analysis that shows that no new worst-case was added with this submission, demonstrate that the devices are substantially equivalent to the predicate.