September 3, 2026

Pace Surgical
% Danielle Besal
Regulatory Consultant
MRC Global, LLC
9160 Hwy. 64 Suite 12
P.O. Box 330
Lakeland, Tennessee 38002

Re: K261647
Trade/Device Name: Tempo Plating System; Ultra Compression Screw 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: August 5, 2026
Received: August 5, 2026

Dear Danielle Besal:

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

CHRISTOPHER FERREIRA -S

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.	K261647

Please provide the device trade name(s).

Tempo Plating System
;
Ultra Compression Screw System

Please provide your Indications for Use below.

The Tempo Plating System is indicated for use in stabilization and fixation of fractures or osteotomies; intra- and extra-articular fractures, joint depression, and multifragmentary fractures; revision procedures, joint fusion, and reconstruction of small bones of the toes, feet, and ankles, including the distal tibia, talus, and calcaneus, as well as the fingers, hands, and wrists. The system can be used in adult patients. Specific examples include:

Forefoot:
- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Metatarsal or phalangeal fractures and osteotomies
- Lesser metatarsal fractures (e.g. Weil)
- Fifth metatarsal fractures (e.g. Jones Fracture)

Mid/Hindfoot:
- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Subtalar Fusion
- Medial Column Fusion
- Cuneiform Fracture
- Cuboid Fracture
- Navicular Fracture

First metatarsal osteotomies for hallux valgus correction, including:
- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic Osteotomy
- Proximal Osteotomy (Chevron and Rotational Oblique)
- Distal Osteotomy (Chevron / Austin)

Arthrodesis of the first metatarsophalangeal joint (MTP), including:
- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot:
- Lateral Column Lengthing (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Calcaneal Slide Osteotomy

Charcot:
• Medial column fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot)
• Lateral column fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

In addition, the non-locking screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

The Pace Surgical Ultra™ Compression Screw System is intended for the internal fixation and stabilization of arthrodeses, osteotomies, fractures, and nonunions of the foot and ankle. The System is specifically indicated for:
Fractures and Osteotomies
• Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
• Avulsion fractures and fractures of the 5th metatarsal (i.e. Jones Fracture)
• Talar fractures
• Ankle fractures
• Navicular fractures
• Fractures of the fibula, malleolus, and calcaneus
• Metatarsal and phalangeal osteotomies
• Weil osteotomy
• Calcaneal osteotomy

Fusion resulting from neuropathic osteoarthropathy (Charcot), example:
• Medial and lateral column
• Subtalar, talonavicular, and calcaneocuboid

Arthrodesis and Deformity Correction
• 1st MTP arthrodesis
• Metatarsal deformity correction
• Tarsometatarsal joint arthrodesis
• Naviculocuneiform joint arthrodesis
• Talonavicular arthrodesis
• Subtalar joint arthrodesis
• Triple arthrodesis
• Medial column arthrodesis
• Subtalar joint distraction arthrodesis
• Ankle arthrodesis
• Lateralizing calcaneal osteotomy
• Lateral column lengthening
• Hammertoe

Hallux Valgus Correction
• Fixation of osteotomies (i.e. Akin, Scarf, Chevron)
• Interphalangeal (IP) arthrodesis
• Proximal, midshaft, or distal osteotomy
• Lapidus arthrodesis

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)

?

Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) Summary

Tempo Plating System & Ultra Compression Screw System

September 1, 2026

Company: Pace Surgical
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Primary Contact: Danielle Besal
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901.827.8670
Danielle.Besal@askmrcglobal.com

Company Contact: Bill Rhoda
610.952.0462
rhoda@runwayhc.com

Trade Name:	Tempo Plating System; Ultra Compression Screw System
Common Name:	Plate, Fixation, Bone; Screw, Fixation, Bone
Classification:	Class II
Regulation Number:	21 CFR 888.3030 (Primary) Single/multiple component metallic bone fixation appliances and accessories; 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Panel:	Orthopedic
Product Code:	HRS (Primary), HWC
Predicate Devices:	K250952, Baby Gorilla®/Gorilla® Plating System (Primary) K251555, Ultra™ Compression Screw System K203011, Monster Screw System

Device Description:

The Pace Surgical Tempo Plating System is a plating system designed for fixation of bones and joints in the toes, feet, and ankles, including the distal tibia, talus, and calcaneus, as well as the fingers, hands, and wrists. All implants are manufactured from titanium alloy per ASTM F136. All implants are available in multiple sizes and configurations to accommodate varying patient anatomy.

The Ultra Compression Snap-Off Screws are a line addition to the Ultra Compression Screw System, which is intended for use in internal fixation and stabilization of arthrodeses, osteotomies, fractures, and non-unions of the foot and ankle, including the forefoot, midfoot, hindfoot, and ankle applications. The snap-off screws are manufactured from titanium alloy per ASTM F136.

Indications for Use:

The Tempo Plating System is indicated for use in stabilization and fixation of fractures or osteotomies; intra- and extra-articular fractures, joint depression, and multifragmentary fractures; revision procedures, joint fusion, and reconstruction of small bones of the toes, feet, and ankles, including the distal tibia, talus, and calcaneus, as well as the fingers, hands, and wrists. The system can be used in adult patients. The plates are indicated for use in bones of the feet including the toes, midfoot, and hindfoot (talus and calcaneus). Specific examples include:

Forefoot:
- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Metatarsal or phalangeal fractures and osteotomies
- Lesser metatarsal fractures (e.g. Weil)
- Fifth metatarsal fractures (e.g. Jones Fracture)

Mid/Hindfoot:
- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
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- Subtalar Fusion
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- Lateral Column Lengthing (Evans Osteotomy)
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Charcot:
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- Lateral column fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

In addition, the non-locking screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

The Pace Surgical Ultra™ Compression Screw System is intended for the internal fixation and stabilization of arthrodeses, osteotomies, fractures, and nonunions of the foot and ankle. The System is specifically indicated for:

Fractures and Osteotomies
- Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
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- Interphalangeal (IP) arthrodesis
- Proximal, midshaft, or distal osteotomy
- Lapidus arthrodesis

Substantial Equivalence:
The subject and predicate devices have similar indications for use. The subject devices are similar in technological characteristics to the respective predicate devices. The materials are identical to the predicate and the device geometry and sizing is similar to that of the predicate device offerings. The subject system includes plate and screw designs intended for the same anatomical locations as the range available for the predicate device.

Performance Testing:
Mechanical testing per ASTM F543 (torsional strength, driving torque, axial pullout strength) and ASTM F382 (static bending) were conducted on the subject devices.

Clinical data were not applicable.

The subject screws met the performance criteria in FDA Guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway;" therefore, can be considered equivalent to the predicate devices in terms of performance. The subject plates demonstrated substantially equivalent performance to the predicate plates in mechanical testing.

Conclusion:
The subject devices are considered substantially equivalent to the predicate devices (K250952, K251555, K203011).