October 12, 2023

Paragon 28 Inc.
Haylie Hertz
Associate Manager of Regulatory Affairs
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K231231
Trade/Device Name: MR Safety and Compatibility Testing and Labeling for Paragon 28 Orthopedic Fixation Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS, HTN, KTW, HSB, HTY, HSN
Dated: September 12, 2023
Received: September 13, 2023

Dear Haylie Hertz:

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,

Tejen D. Soni -S

For
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: **List of Cleared Devices in K231231**

List of Cleared Devices in K231231

1. Monster® Screw System – MR Conditional
2. Baby Gorilla®/Gorilla® Plating System – MR Conditional
3. Small Bone Phantom® Intramedullary Nail System; TTC Phantom® Intramedullary Nail System – MR Conditional
4. Phantom® Hindfoot TTC/TC Nail System – MR Conditional
5. HammerTube System – MR Conditional
6. Apex 3D Total Ankle Replacement System– MR Conditional

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231231

Device Name
Monster Screw System

Indications for Use *(Describe)*

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

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

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

Arthrodesis/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

Fusion resulting from neuropathic osteoarthropathy (Charcot) such as:
- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

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.

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K231231

Device Name
Baby Gorilla / Gorilla Plating System

Indications for Use *(Describe)*

The Baby Gorilla® / Gorilla® Bone Plates and Bone Screws of the Baby Gorilla® and Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary 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 both adult and pediatric 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

Ankle
• Lateral Malleolar Fractures
• Syndesmosis Injuries
• Medial Malleolar Fractures and Osteotomies
• Bi-Malleolar Fractures
• Tri-Malleolar Fractures
• Posterior Malleolar Fractures
• Distal Anterior Tibia Fractures
• Vertical Shear Fractures of the Medial Malleolus
• Pilon Fractures
• Distal Tibia Shaft Fractures
• Distal Fibula Shaft Fractures
• Distal Tibia Periarticular Fractures
• Medial Malleolar Avulsion Fractures
• Lateral Malleolar Avulsion Fractures
• Tibiotalocalcaneal Joint Arthrodesis
• Tibiocalcaneal Arthrodesis
• Supramalleolar Osteotomy

• Fibular Osteotomy

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 titanium screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231231

Device Name
Phantom Small Bone Intramedullary Nail System

Indications for Use *(Describe)*

The Phantom® Small Bone Intramedullary Nail System is indicated for use in stabilization and fixation of the small bones of the feet and ankle for the treatment of fractures, osteotomies, nonunions, pseudarthroses and malunions by revision, joint fusion or reconstruction procedures.

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)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231231

Device Name
Phantom Hindfoot TTC/TC Nail System

Indications for Use *(Describe)*

The Phantom® Hindfoot TTC/TC Nail System is intended for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot.
Examples of specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision of failed ankle arthrodesis
- Revision of failed total ankle arthroplasty
- Talar deficiency conditions such as avascular necrosis of the talus (requiring tibiocalcaneal arthrodesis)
- Neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid arthritis
- Osteoarthritis
- Nonunions or pseudarthrosis of hindfoot and distal tibia
- Trauma (severe or malunited tibial pilon fracture)
- Charcot foot (neuroarthropathy)
- Severe end-stage degenerative arthritis
- Instability and skeletal defects after tumor resection
- Pantalar arthrodesis
- Severe foot/ankle deformity

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231231

Device Name
Phantom Hindfoot TTC/TC Nail System

Indications for Use *(Describe)*

The Phantom® Hindfoot TTC/TC Nail System is indicated for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot.
Examples of specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision of failed ankle arthrodesis
- Revision of failed total ankle arthroplasty
- Talar deficiency conditions such as avascular necrosis of the talus (requiring tibiocalcaneal arthrodesis)
- Neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid arthritis
- Osteoarthritis
- Nonunions or pseudarthrosis of hindfoot and distal tibia
- Trauma (severe or malunited tibial pilon fracture)
- Charcot foot (neuroarthropathy)
- Severe end-stage degenerative arthritis
- Instability and skeletal defects after tumor resection
- Pantalar arthrodesis
- Severe foot/ankle deformity

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231231

Device Name
APEX 3D Total Ankle Replacement System

Indications for Use *(Describe)*

The APEX 3D™ Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. In the United States, components are intended for cemented use only.

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)

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K231231

510(K) SUMMARY

Bundled Traditional 510(k) for MR Safety and Compatibility Testing and Labeling Updates for Paragon 28 Orthopedic Fixation Devices:

510(k) Number:	K231231
Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Haylie Hertz Associate Manager of Regulatory Affairs Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 303-720-0017 hhertz@paragon28.com
Date Prepared:	October 10, 2023
Device Trade Names:	Monster® Screw System Baby Gorilla® / Gorilla® Plating System Phantom® Small Bone Intramedullary Nail System Phantom® Hindfoot TTC/TC Nail System HammerTube™ System APEX 3D™ Total Ankle Replacement System
Device Class:	Class II
Primary Predicate:	Monster® Screw System (K203011)
Additional Predicates:	Baby Gorilla® / Gorilla® Plating System (K222194) Phantom® Small Bone Intramedullary Nail System (K182307) Phantom® Hindfoot TTC/TC Nail System (K210869) HammerTube™ System (K171715) APEX 3D™ Total Ankle Replacement System (K210390)

Device Description:

Monster® Screw System

The Monster® Screw System is comprised of threaded bone screws (Ti Alloy or Stainless Steel) offered in 2.0mm to 9.5mm diameters (in 0.5mm increments). In addition, a 2.7mm diameter is also part of the system. The overall screw length ranges from 8mm (for smaller diameters) thru 200mm (for larger diameters). The screws are available in a variety of designs including fully or partially threaded, self-drilling or blunt, cannulated or solid, and headed or headless. Sized-matched washers are also available.

Baby Gorilla® / Gorilla® Plating System

The Baby Gorilla® / Gorilla® Plating System is comprised of bone plates, threaded bone screws, and washers. Gorilla® Plates are offered in "mini" and "standard" set sizes in a variety of shapes based upon the anatomical fixation required. Screws are also offered in "mini" and "standard" sets and, in addition, in locking and non-locking versions. Size-matched washers are available for use with the non0locking screws when the latter are used for fixation without the plates. Size-matched plate washers are also available for use with plate holes when there is no desire to use a screw. The Baby Gorilla® / Gorilla® Plating System implants are manufactured from medical grade titanium (per ASTM F67), stainless steel (per ASTM F138), and titanium alloy (per ASTM F136).

Phantom® Small Bone Intramedullary Nail System

The Phantom® Small Bone Intramedullary Nail System is comprised of small bone intramedullary nails, locking screws and threaded pegs. The Phantom® nails are offered in a variety of lengths to accommodate variations in patient anatomy. The Phantom® threaded pegs and locking screws insert through the intramedullary nail to secure the construct. These are offered in varying lengths to accommodate the anatomical fixation required. The system includes instruments for implantation.

Phantom® Hindfoot TTC/TC Nail System

The Phantom® Hindfoot TTC/TC Nail System is comprised of intramedullary nails, screws and accessory components. The Phantom® nails are offered in a variety of sizes lengths, and configurations to accommodate variations in patient anatomy. The Phantom® screws insert through the intramedullary nail to secure the construct. These are offered in varying lengths to accommodate the anatomical fixation required.

HammerTube™ System

The HammerTube™ System includes HammerTube™ and K-Wire implants. The HammerTube™ is a commercially pure titanium

Device Description (continued):

plasma sprayed PEEK cylinder in varying diameters, lengths, and angles. The K-Wires are stainless steel and double trocar pointed. The implants are sold sterile.

APEX 3D Total Ankle Replacement System

The APEX 3D™ Total Ankle Replacement System is a cemented, fixed bearing device comprised of a tibial component, a talar component and an Ultra-High Molecular Weight Polyethylene (UHMWPE) component used for ankle joint replacement. Components are available in varying sizes and design configurations intended for both primary and revision applications.

Classification and Product Codes:

Monster® Screw System	21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener	HWC
Baby Gorilla® / Gorilla® Plating System	21 CFR 888.3030; Plate, Fixation, Bone 21 CFR 888.3040; Screw, Fixation, Bone 21 CFR 888.3030; Washer, Bolt Nut	HRS HWC HTN
Phantom® Small Bone Intramedullary Nail System	21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener 21 CFR 888.3030; Appliance, fixation, nail/blade/plate combination, single component	HWC KTW
Phantom® Hindfoot TTC/TC Nail System	21 CFR 888.3020; Rod, fixation, intramedullary and accessories 21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener	HSB HWC
HammerTube™ System	21 CFR 888.3040; Pin, Fixation, Smooth	HTY
APEX 3D™ Total Ankle Replacement System	21 CFR 888.3110; Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer	HSN

Indications for Use:

Monster® Screw System

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

Indications for Use (continued):

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

Hallux Valgus Correction

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

Arthrodesis/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

Fusion resulting from neuropathic osteoarthropathy (Charcot) such as:

- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

Baby Gorilla® / Gorilla® Plating System

The Baby Gorilla® / Gorilla® Bone Plates and Bone Screws of the Baby Gorilla® and Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, talus, and calcaneus,

Indications for Use (continued):

as well as the fingers, hands, and wrists. The system can be used in both adult and pediatric 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

Ankle

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures and Osteotomies
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures
- Tibiotalocalcaneal Joint Arthrodesis
- Tibiocalcaneal Arthrodesis

Indications for Use (continued):

- Supramalleolar Osteotomy
- Fibular Osteotomy

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 titanium screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

Phantom® Small Bone Intramedullary Nail System

The Phantom® Small Bone Intramedullary Nail System is indicated for use in stabilization and fixation of the small bones of the feet and ankle for the treatment of fractures, osteotomies, nonunions, pseudarthroses and malunions by revision, joint fusion or reconstruction procedures.

Phantom® Hindfoot TTC/TC Nail System

The Phantom® Hindfoot TTC/TC Nail System is indicated for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot.

Examples of specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision of failed ankle arthrodesis
- Revision of failed total ankle arthroplasty
- Talar deficiency conditions such as avascular necrosis of the talus (requiring tibiocalcaneal arthrodesis)
- Neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid arthritis
- Osteoarthritis
- Nonunions or pseudarthrosis of hindfoot and distal tibia
- Trauma (severe or malunited tibial pilon fracture)
- Charcot foot (neuroarthropathy)
- Severe end-stage degenerative arthritis
- Instability and skeletal defects after tumor resection
- Pantalar arthrodesis
- Severe foot/ankle deformity

HammerTube™ System

The HammerTube™ System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures.

The cannulated and solid HammerTube™ implants may be used without any other additional device. The cannulated implants may be used with K-Wires for delivery of implants or for the temporary stabilization of nearby joints, such as the metatarsophalangeal joint.

The implantable K-Wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-Wires are indicated as guide pines for insertion of instruments and implants in the HammerTube™ System.

APEX 3D™ Total Ankle Replacement System

The APEX 3D™ Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. Components are intended for cemented use only.

Substantial Equivalence:

The purpose of this Bundled Traditional 510(k) is to obtain clearance of Magnetic Resonance (MR) safety and compatibility testing and Magnetic Resonance Imaging (MRI) Safety Information updates to the labeling of the previously cleared and legally marketed Paragon 28 Orthopedic Fixation Devices. There are no other indications for use, design, material, processing, performance, or labeling modifications subject to the submission.

The intended use, principle of operation and fundamental scientific technology of the modified devices are identical to the predicate devices. The MR safety and compatibility performance and labeling modifications were accomplished via testing in the MRI environment and updated labeling per the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*" issued May 20, 2021. The data demonstrate substantial equivalence and the subject modifications do not raise new issues of safety or effectiveness.

Performance Testing:

MR Safety and Compatibility Testing has been completed and presented in the submission as recommended in the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*" issued May 20, 2021, including FDA-recognized standards tests for the following potential hazards:

- Image Artifact per ASTM F2119 *Test Method for Evaluation of MR Image Artifacts from Passive Implants*
- Magnetically Induced Displacement Force per ASTM F2052 *Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- Magnetically Induced Torque per ASTM F2213 *Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- Radiofrequency (RF) Induced Heating per ASTM F2182 *Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging*

Based on the results, each device will be labeled as "MR Conditional" with MRI Safety Information in the instructions for use as described in ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.*

Conclusions:

Monster® Screw System

The subject device Monster® Screw System is substantially equivalent to the previously cleared predicate device Monster® Screw System (K203011).

Baby Gorilla® / Gorilla® Plating System

The subject device Baby Gorilla® / Gorilla® Plating System is substantially equivalent to the previously cleared predicate device Baby Gorilla® / Gorilla® Plating System (K222194).

Phantom® Small Bone Intramedullary Nail System

The subject device Phantom® Small Bone Intramedullary Nail System is substantially equivalent to the previously cleared predicate device Phantom® Small Bone Intramedullary Nail System (K182307).

Phantom® Hindfoot TTC/TC Nail System

The subject device Phantom® Hindfoot TTC/TC Nail System is substantially equivalent to the previously cleared predicate device Phantom® Hindfoot TTC/TC Nail System (K210869).

HammerTube™ System

The subject device HammerTube™ System is substantially equivalent to the previously cleared predicate device HammerTube™ System (K171715).

APEX 3D™ Total Ankle Replacement System

The subject device APEX 3D™ Total Ankle Replacement System is substantially equivalent to the previously cleared predicate device APEX 3D™ Total Ankle Replacement System (K210390).

The subject devices possess identical indications for use, technological characteristics, and principles of operation as the predicates. The proposed device modification (MR Conditional patient safety information) does not raise new issues of safety or effectiveness and has been fully evaluated per the FDA Guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*" issued May 20, 2021. The subject devices are substantially equivalent to the legally marketed, predicate Paragon 28 Orthopedic Fixation Devices.