DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K190365

Device Name
Baby Gorilla®/Gorilla® Plating System

Indications for Use *(Describe)*
The Baby Gorilla®/Gorilla® Bone Plates and Bone Screws of the Baby Gorilla®/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 shortening osteotomies (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 Fusions
• 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
• Tibiotalar 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 Lengthening (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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