510(k) Summary

Date:	March 18th, 2019
510(k) Number:	K190365
Sponsor:	Paragon 28, Inc. 4B Inverness Ct. E., STE 280 Englewood, Colorado 80112 Phone: (888) 728-1888 Fax: (888) 728-1220
Sponsor contact:	Eric Lintula, Director of Regulatory Affairs
Trade Name:	Baby Gorilla®/Gorilla® Plating System
Regulatory Class:	Class II
Regulation, Product Code, Classification, and Common Name:	888.3030, HRS, Plate, Fixation, Bone 888.3040, HWC, Screw, Fixation, Bone 888.3030, HTN, Washer, Nut Bolt
Device Description:	The Baby Gorilla®/Gorilla® Plating System implants are internal fixation systems. 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 non-locking 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.
Compatible Devices:	K124027, K151418, K153378 Monster® Screw System
Indications for Use:	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 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
- 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.
Materials:	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).
Primary Predicate:	K182148, BABY GORILLA®/GORILLA® Plating System (formerly ParaLock Plating System)
Additional Predicates:	K152974, ORTHOLOC® 3Di Foot Plating Reconstruction System K151235, Medline Foot Plates and Screws K163039, ORTHOLOC® 3Di Small Bones Plating System K162674, BioPro Foot Plating Systems K163044, ORTHOLOC® 3Di Ankle Fracture System K163650, ORTHOLOC® 3Di Ankle Fusion Plating System K140792, SALVATION™ 3Di Plating System K140741, SALVATION™ Beams and Bolts System
Comparison to Predicate Indications:	The subject Baby Gorilla®/Gorilla® Plating System and the predicate systems are intended to be used for stabilization and fixation of fractures, osteotomies, revision procedures, joint fusion, and reconstruction of bones. All indications for the subject device are within the indications of the predicate devices.
Comparison to Predicate Technological Characteristics:	The subject Baby Gorilla®/Gorilla® Plating System components possess the same technological characteristics as the predicate devices. These include: • performance, • basic design, • material, manufacturing and • sizes (dimensions are comparable to those offered by the predicate systems). Differences between the Baby Gorilla®/Gorilla® Plating System implants and the predicate devices were shown not to raise new questions of safety and effectiveness. Therefore, the fundamental

	scientific technology of the subject Baby Gorilla®/Gorilla® Plating System components is similar to previously cleared devices.
Performance Data:	Engineering analysis is presented to provide evidence that the original testing and subsequent performance is not adversely affected by the modifications to the subject devices. The results of the analysis demonstrated the modified designs are substantially equivalent to the predicate devices.
Conclusion:	The modified Baby Gorilla®/Gorilla® Plating System possessed the same indications for use and technological characteristics as predicate marketed devices. Therefore, the Baby Gorilla®/Gorilla® Plating System is substantially equivalent to the predicate devices with respect to their indications for use, technical characteristics, and function.