Paragon 28, Inc.
Eric Lintula
Director of Regulatory Affairs
4B Inverness Ct. E, STE 280
Englewood, Colorado 80112

September 9, 2018

Re: K182148
Trade/Device Name: SILVERBACK Gorilla 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, HTN
Dated: August 2, 2018
Received: August 8, 2018

Dear Eric Lintula:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K182148

Device Name
SILVERBACK 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. The system can be used in both adult and pediatric patients.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**

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| **Date:** | August 2nd, 2018 |
| **Sponsor:** | Paragon 28, Inc.<br>4B Inverness Ct. E., STE 280<br>Englewood, Colorado 80112<br>Phone: (888) 728-1888<br>Fax: (888) 728-1220 |
| **Sponsor contact:** | Eric Lintula<br>Senior Director of Quality and Regulatory Affairs |
| **Trade Names:** | SILVERBACK Gorilla Plating System |
| **Regulatory Class:** | Class II |
| **Regulation, Product Code, Classification, and Common Name:** | 888.3030, HRS, Single/multiple component metallic bone fixation appliances and accessories, bone plate system<br><br>888.3040, HWC, Smooth or threaded metallic bone fixation fastener, bone screw<br><br>888.3030, HTN, Single/multiple component metallic bone fixation accessories, washer |
| **Device Description:** | The BABY GORILLA®/GORILLA® implants are lower extremity 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. |
| **Materials:** | The BABY GORILLA®/GORILLA® implants are manufactured from medical grade titanium (per ASTM F67), stainless steel (per ASTM F138), and titanium alloy (per ASTM F136). |
| **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. The system can be used in both adult and pediatric patients. |

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| | 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. |
| **Primary Predicate:** | K140397, BABY GORILLA®/GORILLA® Plating System (formerly ParaLock Plating System), Paragon 28, Inc. |
| **Additional Predicates:** | K172886, BABY GORILLA®/GORILLA® Breakaway Screw System, Paragon 28, Inc.<br>K121425, ORTHOLOC™ 3Di Ankle Fusion System, Wright Medical Technology, Inc.<br>K141735, Ankle Fusion Plating System, Arthrex, Inc. |
| **Performance Data:** | Engineering analysis is presented to provide evidence that the original testing and subsequence performance is not adversely affected by the geometry of the modified plates, screws, and washers.<br><br>The results of the analysis demonstrated the modified designs are substantially equivalent to the predicate devices. |
| **Technological Characteristics:** | The modified Gorilla plates, screws, and washers possess the same technological characteristics as the predicate devices. These include:<br>• performance,<br>• basic design,<br>• material, manufacturing and<br>• sizes (dimensions are comparable to those offered by the predicate systems).<br>Therefore, the fundamental scientific technology of the modified Gorilla Plates, Screws, and Washers is similar to previously cleared devices. |
| **Conclusion:** | The modified Gorilla Plates, Screws, and Washers possess indications for use and technological characteristics that are the same as the predicate devices. Therefore, the modified Gorilla Plates, Screws, and Washers are substantially equivalent to the predicates. |