March 1, 2018

Panther Orthopedics, Inc.
% Allison C. Komiyama, Ph.D., R.A.C.
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn Street
San Diego, California 92104

Re: K171703
Trade/Device Name: PUMA System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: January 26, 2018
Received: January 26, 2018

Dear Dr. Komiyama:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171703

Device Name
PUMA System

Indications for Use *(Describe)*
The PUMA System is intended as an adjunct in fracture repair involving metaphyseal, and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

The PUMA System when used for fixation of bone-to-bone or soft tissue-to-bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Specifically, the PUMA System is indicated to provide fixation during the healing process for the following:
- Fixation of Syndesmosis disruptions in connection with Weber B and C ankle fractures.
- Fixation of Syndesmosis disruptions in connection with dorsal distal radioulnar ligament (DRUL) disruptions.
- Tarsometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc Injury.
- Hallux Valgus reconstruction by providing for the reduction of 1st and 2nd metatarsal intermetatarsal angle.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
K171703

DATE PREPARED
February 27, 2018

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
PUMA System

COMMON NAME
Washer, Bolt Nut

DEVICE CLASSIFICATION
Single/multiple component metallic bone fixation appliances and accessories
(21 CFR 888.3030, Product Code HTN, Class II)

PREMARKET REVIEW
Orthopedic Review Panel

INDICATIONS FOR USE
The PUMA System is intended as an adjunct in fracture repair involving metaphyseal, and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

The PUMA System when used for fixation of bone-to-bone or soft tissue-to-bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Specifically, the PUMA System is indicated to provide fixation during the healing process for the following:

- Fixation of Syndesmosis disruptions in connection with Weber B and C ankle fractures.
- Fixation of Syndesmosis disruptions in connection with dorsal distal radioulnar ligament (DRUL) disruptions.
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- Hallux Valgus reconstruction by providing for the reduction of 1st and 2nd metatarsal intermetatarsal angle.

DEVICE DESCRIPTION

The PUMA System comprises three components: one suture (PUMA Body) made of a nickel titanium alloy (nitinol), and two anchors (PUMA Anchors) made of polyether-ether-ketone (PEEK). The PUMA Body is inserted through bones or soft tissues that need to be stabilized. Once placed, the device secures the bone and/or tissue by means of the PUMA Anchors affixed to each side of the Body. The elastic/superelastic shape characteristic of the nitinol confers some flexibility while maintaining the stability of the PUMA System.

PREDICATE DEVICE IDENTIFICATION

The PUMA System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K090107	Mini TightRope / Arthrex, Inc.	✓
K043248	TightRope Syndesmosis Device / Arthrex, Inc.	
K142727	CrossCLIP Implant System / OrthoDiscovery Group, LLC	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the PUMA System. The following tests were performed to demonstrate safety based on current industry standards:

- Biocompatibility risk assessment per ISO 10993-1
- Bacterial Endotoxin Testing per ANSI/AAMI ST72
- Extractable/Leachable Chemical Analysis and Toxicological Risk Assessment
- Pull-out Force
- Cyclic Fatigue Testing
- Tensile Testing (pre- and post-cyclic fatigue testing)
- Corrosion Testing (on the final trimmed device)

The results of these tests indicate that the PUMA System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

The subject device has the same intended use, identical indications for use, and similar design as the devices cleared in K090107 and K043248. The subject device uses similar materials as the device cleared in K142727. Overall, the subject and predicate devices have similar technological characteristics (a body that generates compression that is secured to tissue or bone) to the devices cleared in K090107, K043248, and K142727. Any differences in technological characteristics do not raise different questions of safety and effectiveness, and performance data demonstrate substantial equivalence to the predicates.

CONCLUSION

Based on the testing performed, including biocompatibility, pull-out force, and tensile strength, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed PUMA System are assessed to be substantially equivalent to the predicate devices. The subject device is considered as safe and effective for its intended use as the predicate device.