DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 24, 2017

Panatheon Medical
% Lee Strnad
Management Representative
Intrepid Orthopedics
3046 Brecksville Rd, Ste 4
Richfield, OH 44286

Re: K162154
Trade/Device Name: Panatheon Medical Balanced 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
Dated: April 1, 2017
Received: April 3, 2017

Dear Mr. Strnad:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K162154

Device Name
Pantheon Medical Balanced Plating System

Indications for Use *(Describe)*
The Pantheon Medical Balanced Plating System is intended for fixation of fractures, revision procedures, joint fusion, non-unions, and reconstruction of orthopedic small bone extremities. This system is not intended for spinal use.

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.

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05. 510(k) Summary

Submitter Information

Applicant: Pantheon Medical
1505 Federal Street, Suite 300
Dallas, Texas 75201

Contact Person: Lee A. Strnad
Management Representative
Intrepid Orthopedics
3046 Brecksville Rd, Ste 4
Richfield, OH 44286
(330) 659-0855

Date Prepared: 4/18/17

Name of Device: Pantheon Medical Balanced Plating System

Common Name: Bone Fixation Plate

Classification Name Single/Multiple component metallic bone fixation appliances and accessories (per 21 CFR 888.3030), Smooth or threaded metallic bone fixation fastener (per 21 CFR 888.3040)

Product Code/Panel: HRS/Orthopedics, HWC

Predicate Devices: Mondeal Extremity Bone Fixation System (K072740), Mondeal CONTOUR HO System (K050657)

Intended Use:

The Pantheon Medical Balanced Plating System is intended for fixation of fractures, revision procedures, joint fusion, non-unions, and reconstruction of orthopedic small bone extremities. This system is not intended for spinal use.

Device Description

PANTHEON

05. 510(k) Summary

The Pantheon Medical Balanced Plating System consists of multiple plate families of various anatomical sizes and shapes, 2.7mm and 3.5mm locking and non-locking screws which mate into the plates, as well as a 4.0mm compression screw that is utilized with the Lapidus plate. Various instruments are also included to assist in implanting the system.

Technological Characteristics

The Pantheon Medical Balanced Plating System have the same intended use as the predicate devices. The Pantheon Medical Balanced Plating System have similar indications for use as the predicate devices. The Pantheon Medical Balanced Plating System are manufactured from the same materials as the predicate devices. Pantheon Medical Balanced Plating System implants are manufactured from Ti-6Al-4V per ASTM F-136. The range of sizes of the Pantheon Medical Balanced Plating System are similar to the predicate devices.

Non-Clinical Performance Data Summary

1. ASTM F-543
2. ASTM F-382

Clinical Performance Data Summary

No clinical testing was required.

Non-Clinical and Clinical Performance Data Conclusions

Based on testing results and the comparisons provided, the Pantheon Medical Balanced Plating System are considered substantially equivalent to the Mondeal Extremity Bone Fixation System in material, construction, and performance characteristics.