November 2, 2018

Integra Lifesciences Corporation
Blesson Abraham
Senior Regulatory Affairs Associate
11101 Metric Blvd.
Austin, Texas 78758

Re: K181639
Trade/Device Name: Panta 2 Arthrodesis Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 10, 2018
Received: October 12, 2018

Dear Blesson Abraham:

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,

Vincent J. Devlin -S

for
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)*

K181639

Device Name
Panta 2 Nail Arthrodesis System

Indications for Use *(Describe)*

The Panta 2 Nail Arthrodesis System is intended for use in tibiotalocalcaneal arthrodesis and treatment of trauma to the hindfoot and distal tibia. Indications include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions (requiring a tibiocalcaneal arthrodesis)
- Avascular necrosis of the talus
- Neuroarthropathy or neuropathic ankle deformity
- Severe deformity as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint.

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.

Integra Lifesciences Corporation – Special 510(k)
Integra Panta 2 Arthrodesis Nail System

510(k) Summary

Sponsor	**Integra Lifesciences Corp.** **Ascension Orthopedics, Inc.** 11101 Metric Blvd. Austin, TX 78758
Establishment Number	3014207283
Point of Contact	Blesson Abraham Senior Regulatory Affairs Specialist 11101 Metric Blvd. Austin, TX 78758 512-368-1423
Date	July 10, 2018
Trade Name	Panta 2 Arthrodesis Nail System
Classification Name	Intramedullary Fixation Rod
Classification Panel	Orthopedic
Classification	Class II
Regulation	21 CFR 888.3020
Product Code	HSB
Predicate Device	K091788 Newdeal Panta® Nail (10 mm and Panta® Nail XL) System, currently marketed under Integra as the Panta Arthrodesis Nail System.
Device Description	The Panta 2 Arthrodesis Nail System (Panta 2) is used to perform a tibio-talo-calcaneal arthrodesis, a procedure undertaken for hindfoot problems that affect both the ankle and subtalar joints. The aim is to achieve fusion of the bones using a retrograde Nail that allows re-alignment of the foot on the weight-bearing axis, correction of coronal and sagittal plane deformities, rotational stability as well as axial compression. The Panta 2 System includes instrumentation which allows placement of screws through the central Nail and enables application of compression along with multi-planar screw fixation in the tibia, the talus, and the calcaneus.

Integra Lifesciences Corporation – Special 510(k)
Integra Panta 2 Arthrodesis Nail System

<table>
<tr><td></td><td></td></tr>
<tr><td>Intended Use/
Indications for Use</td><td>The Panta 2 Arthrodesis Nail System is intended for use in tibiotalocalcaneal arthrodesis and treatment of trauma to the hindfoot and distal tibia. Indications include:
Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
Rheumatoid arthritis
Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body
Revision of failed total ankle arthroplasty with subtalar intrusion
Talar deficiency conditions (requiring a tibiocalcaneal arthrodesis)
Avascular necrosis of the talus
Neuroarthropathy or neuropathic ankle deformity
Severe deformity as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
Severe pilon fractures with trauma to the subtalar joint.</td></tr>
<tr><td>Nonclinical
Performance Data</td><td>The Panta 2 Arthrodesis Nail System implants were subjected to verification testing per required standards to establish substantial equivalent performance in comparison to the predicate device.
<table>
<tr><th>No.</th><th>Testing Description</th><th>Standard</th><th>Results</th></tr>
<tr><td>1</td><td>Nail - Bending Static Comparison Test</td><td>ASTM F1264</td><td rowspan="3">The Panta 2 System Nail performed substantially equivalent when compared to the predicate system Nail.</td></tr>
<tr><td>2</td><td>Nail - Bending Fatigue Life Comparison Test</td><td>ASTM F1264</td></tr>
<tr><td>3</td><td>Nail - Static Torsional Strength Comparison Test</td><td>ASTM F1264</td></tr>
<tr><td>4</td><td>Screws - Bending Fatigue Strength Test</td><td>ASTM F1264</td><td>The Panta 2 System screws performed substantially equivalent when compared to the predicate system screws.</td></tr>
<tr><td>5</td><td>Screws - Torsional Properties Test</td><td>ASTM F543</td><td rowspan="2">The Panta 2 System screws performed to requirements of the identified standards.</td></tr>
<tr><td>6</td><td>Screws – Axial Pullout Strength Test</td><td>ASTM F543</td></tr>
</table></td></tr>
<tr><td>Clinical
Performance Data</td><td>Clinical performance data is not required to demonstrate substantial equivalence to the predicate device.</td></tr>
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Integra Lifesciences Corporation – Special 510(k)
Integra Panta 2 Arthrodesis Nail System

Substantial Equivalence Conclusion	Basis of substantial equivalence of the modified device and predicate device established on the following: The Panta 2 and Panta 1 Systems have the following similarities: • Both systems have the same Indications for Use**.** The intended patient population and indications for use of the Panta 1 Arthrodesis Nail System are unchanged. • Both systems operate using the same fundamental scientific technology. • Both systems incorporate the same basic implant design. • Both systems use the same methods of sterilization. • Both systems use the same operational principles for the surgical implantation of the IM Nails, Screws, and End Caps. The Panta 2 and Panta 1 have the following differences: • Conformance to implant material from ISO 5832 to ASTM 136 • Minor dimensional differences in the nail design • Additional screw sizes added for fully threaded screws • Reduce available sizes of partially threaded screws • Minor change to the anodization and dimensional characteristics of the screws • Reduce available end cap sizes and modify anodization of the end cap Evaluation of the risks and performance data based on the differences between the subject device and predicate does not raise any new issues or concerns related to safety or effectiveness. It is concluded that the modified device, the Panta 2 Arthrodesis Nail System, is as safe and effective as the predicate device for its intended use, and is substantially equivalent to the legally marketed predicate device, the Newdeal Panta® Nail (10 mm and Panta® Nail XL) System.