Ascension Orthopedics, Inc.
Divya Savant
Regulatory Affairs Specialist
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K182878
Trade/Device Name: Integra Salto Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: November 20, 2018
Received: November 27, 2018

Dear Divya Savant:

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,

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

Digitally signed by Peter G. Allen -S
Date: 2018.12.18 12:57:01 -05'00'

Enclosure
Indications for Use

510(k) Number (if known)

K182878

Device Name

Integra Salto Total Ankle System

Indications for Use (Describe)

Salto Talaris Total Ankle Prosthesis: The Salto Talaris Total Ankle Prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Components are intended for cemented use only.

Integra XT Revision Ankle Replacement System: The Integra XT Revision Ankle Replacement System is indicated as a total ankle replacement in revision surgeries only for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Components are intended for cemented use only.

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.

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510(k) Summary

Sponsor: Ascension Orthopedics
11101 Metric Blvd
Austin, Texas 78758

Establishment Number: 3014207283

Point of Contact: Divya Savant
Specialist, Regulatory Affairs
609-936-6968
311 Enterprise Drive
Plainsboro, NJ 08536

Date: 12/7/2018

<table>
<thead>
<tr>
<th>Trade Name (s)</th>
<th>Integra Salto Total Ankle System: Salto Talaris Total Ankle Prosthesis &amp; Integra XT Revision Ankle Replacement System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Total Ankle Prosthesis</td>
</tr>
<tr>
<td>Classification Panel</td>
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<tr>
<td>Classification</td>
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<tr>
<td>Classification Name</td>
<td>Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis</td>
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<tr>
<td>Regulation</td>
<td>21 CFR 888.3110</td>
</tr>
<tr>
<td>Product Code</td>
<td>HSN</td>
</tr>
<tr>
<td>Predicate Device</td>
<td>K153452: Salto Talaris, Salto XT</td>
</tr>
<tr>
<td>Reference Device</td>
<td>K151459: Integra Cadence Total Ankle Replacement System</td>
</tr>
</tbody>
</table>

Device Description: The Integra Salto Total Ankle System (Salto Talaris Total Ankle Prosthesis and the Integra XT Revision Ankle Replacement System) is a semi-constrained anatomical design. Both subsystems consist of two mating components: a metal tibial base in association with a conforming polyethylene articulating insert, and a metal talar resurfacing component.

Intended Use: Salto Talaris Total Ankle Prosthesis: The Salto Talaris Total Ankle Prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Components are intended for cemented use only.
Integra XT Revision Ankle Replacement System: The Integra XT Revision Ankle Replacement System is indicated as a total ankle replacement in revision surgeries only for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Components are intended for cemented use only.

Nonclinical Performance Data

The Salto Talaris Total Ankle Prosthesis and Integra XT Revision Ankle Replacement System were subjected to verification per standard ASTM F2665 to establish equivalent performance in comparison to the predicate device.

1. Tibial Tray Fatigue
2. Tibial Tray/Insert Locking
3. Tibial Tray Bone Fixation
4. Talar Dome Bone Fixation
5. Talar Dome Fatigue

Clinical Performance Data

Clinical performance data is not required to demonstrate substantial equivalence to the predicate device.

Substantial Equivalence Conclusion

Substantial equivalence of the subject device and predicate device is based on the following:

- The modified device and predicate device have the same material.
- The modified devices and predicated devices have the same intended use.
- The devices operate using the same fundamental scientific technology.
- The devices share the same functional and technological characteristics via the same operational principles.
- There are no new questions of safety or effectiveness.

In conclusion, the modified device and predicate device are both semi-constrained, total ankle arthroplasty systems that have the same intended use, fundamental scientific technology, and materials of construction.