December 2, 2019

Integra LifeSciences Corporation
Blesson Abraham
Senior Regulatory Affairs Specialist
11101 Metric Blvd
AUSTIN TX 78758

Re: K190588
Trade/Device Name: Integra TITAN Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: November 1, 2019
Received: November 4, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K190588

Device Name

Integra TITAN Reverse Shoulder System

Indications for Use *(Describe)*

The Integra TITAN Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The TITAN Reverse Shoulder System is indicated for primary fractures, including proximal humeral or revision total shoulder replacement, for the relief of pain and significant disability due to gross rotator cuff deficiency. The glenoid base plate is intended for cementless application with the addition of screws for fixation. The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless 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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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 Ph. No: 512-368-1423
Date	March 6, 2019
Trade Name	Integra TITAN Reverse Shoulder System
Common Name	Reverse Total Shoulder Orthopedic
Classification Panel	Orthopedic
Classification	Class II
Regulation No.	21 CFR 888.3660
Regulation Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Product Code	PHX
Predicate Device	K161189, Integra TITAN Reverse Shoulder System
Device Description	The Integra TITAN Reverse Shoulder System (RSS) is a semi-constrained total shoulder construct. The humeral components consist of humeral stems, reverse bodies of varying heights, and humeral liners. The humeral liners are available in varying thicknesses and constraints to achieve stability and offset of the glenohumeral joint. The variable length reverse bodies and proximally-filling shape are designed to accommodate the natural humeral geometry, providing stable fixation as well as proximal bone loading. The glenoid components are composed of a baseplate secured by a central compression screw and four peripheral screws, two of which can be locked. A glenosphere is attached to the baseplate via taper lock. Glenospheres are available in varying offsets and lateralizations. The implant scope of the RSS is being expanded to include additional options for humeral liners manufactured from highly crosslinked Ultra High Molecular Weight Polyethylene (XLPE) per ASTM F2565. The existing humeral liners are manufactured from conventional UHMWPE per ASTM F648. The change in material allows for improved wear characteristics of the humeral liners.
Intended Use/ Indications for Use	The Integra TITAN Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint

<table>
<tr><td></td><td>replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The TITAN Reverse Shoulder System is indicated for primary fractures, including proximal humeral or revision total shoulder replacement, for the relief of pain and significant disability due to gross rotator cuff deficiency. The glenoid base plate is intended for cementless application with the addition of screws for fixation. The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless use.</td></tr>
<tr><td>Nonclinical Performance Data</td><td>The subject XLPE humeral liners have undergone the following engineering testing to establish substantial equivalence to the predicate humeral liners.
<table>
<tr><th>No.</th><th>Testing Description</th><th>Standard</th></tr>
<tr><td>1</td><td>Full Construct Fatigue Test</td><td>ASTM F1378
ASTM F1875
ASTM F2009</td></tr>
<tr><td>2</td><td>Axial Disassembly Test</td><td rowspan="2">ASTM F1820</td></tr>
<tr><td>3</td><td>Rotational Resistance Test</td></tr>
<tr><td>4</td><td>Scapular Impingement Fatigue Test</td><td>ASTM F1820
ASTM F2003
ASTM F2582
ISO 14242-1
ISO 14242-2</td></tr>
<tr><td>5</td><td>Wear Test and Analysis – XLPE vs. conventional UHMWPE</td><td>ASTM F732
ASTM F2025</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 RSS device.</td></tr>
<tr><td>Substantial Equivalence Conclusion</td><td>Substantial equivalence of the subject humeral liner and predicate humeral liner is based on the following:
• Both devices have the same intended use.
• Both devices operate using the same fundamental scientific technology.
• Both devices share the same functional and technological characteristics via the same operational principles.

Evaluation of the risks and performance data referenced in this 510(k) submission demonstrate that the subject humeral liners are safe and effective for their intended use and substantially equivalent to the cited predicate humeral liners.</td></tr>
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