October 12, 2018

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

Re: K181999
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: August 10, 2018
Received: August 13, 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,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2018.10.12 12:06:16 -04'00'

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)*

K181999

Device Name

Integra TITAN Reverse Shoulder System

Indications for Use *(Describe)*

The 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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Integra Lifesciences Corporation
Integra TITAN Reverse Shoulder System – Line Extension

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 25, 2018
Trade Name	Integra TITAN Reverse Shoulder System
Common Name	Reverse Total Shoulder
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	K173717 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 stems are intended for cemented and cementless use. The scope of the RSS is being expanded via a line extension to include additional options for baseplates, glenospheres, and screws. The baseplate option features

<table>
<tr><td></td><td>a smaller post in comparison to the currently commercialized baseplate options, along with glenospheres that work in conjunction with the baseplate. The baseplate under this line extension is referred to as the Small Post Baseplate (SPB). Additional Star screw options have also been incorporated as part of the line extension.</td></tr>
<tr><td>Intended Use/ Indications for Use</td><td>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.</td></tr>
<tr><td>Nonclinical Performance Data</td><td>The Integra TITAN Reverse Shoulder System (RSS) line extension components (Small Post Baseplate, SPB Glenospheres, and Star Screws) have undergone the following engineering testing to establish substantial equivalence in comparison to the predicate system components.
<table>
<tr><th>No.</th><th>Testing Description</th><th>Standard</th></tr>
<tr><td>1</td><td>SPB & Glenosphere - Axial Taper Disassembly Test</td><td rowspan="2">ASTM F2009</td></tr>
<tr><td>2</td><td>SPB & Glenosphere - Taper Torsion Test</td></tr>
<tr><td>3</td><td>All Implants - Full Construct Fatigue Test</td><td>ASTM F1378
ASTM F1875</td></tr>
<tr><td>4</td><td>SPB – Dynamic Evaluation of Glenoid Loosening or Disassociation Test</td><td>ASTM F2028</td></tr>
<tr><td>5</td><td>Screws - Torsional Properties Test</td><td rowspan="2">ASTM F543</td></tr>
<tr><td>6</td><td>Screws - Axial Pullout Strength Test</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 device and predicate device is based on the following:
The modified and predicate device have exactly 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.</td></tr>
</table>

	Evaluation of the risks and performance data of the subject device does not raise any new issues or concerns related to safety or effectiveness. We have concluded that the subject device components (the Small Post Baseplate, SPB Glenospheres, and Star Screws) are as safe and effective as the predicate RSS device components (Baseplates, Glenospheres, and Screws) for its intended use, and that the system is substantially equivalent to the legally marketed predicate device, the Integra TITAN Total Reverse Shoulder System.