Integra LifeSciences Corporation
Blesson Abraham
Sr. Regulatory Affairs Associate
8700 Cameron Road
Suite 100
Austin, Texas 78754

June 21, 2018

Re: K173717
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: December 4, 2017
Received: December 5, 2017

Dear Mr. 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. 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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173717

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.

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Integra Lifesciences Corporation – Special 510(k)
Integra TITAN Reverse Shoulder System – Coating Change

Section 7: 510(k) Summary

Sponsor	Integra Lifesciences Corp. 311 Enterprise Drive Plainsboro, NJ 08536
Establishment Number	1651501
Point of Contact	Kathleen McGuire Associate, Regulatory Affairs 609-936-7916 311 Enterprise Drive Plainsboro, NJ 08536
Date	December 4, 2017
Trade Name	Integra TITAN Reverse Shoulder System
Common Name	Reverse Total Shoulder
Classification Panel	Orthopedic
Classification	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation	Class II (under 21 CFR 888.3660)
Product Code	PHX
Predicate Device	K161189: Integra TITAN Reverse Shoulder System
Device Description	The TITAN Reverse Total Shoulder System is a semi-constrained total shoulder construct. The humeral components consist of humeral stems, reverse bodies of varying heights, and humeral poly liners. The poly 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.

Integra Lifesciences Corporation – Special 510(k)
Integra TITAN Reverse Shoulder System – Coating Change

Intended Use	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.
Comparison to Predicate	The proposed device is the same as the predicate in terms of fit, form, and function. The sole modification to the system is that the coating on the implant baseplate and body has been changed from vacuum-sintered titanium Asymmatrix™ to titanium plasma spray.
Nonclinical Performance Data	The TITAN Reverse Shoulder System has undergone the following performance testing to confirm the system's ability to perform under anticipated clinical conditions. 1. *Dynamic Evaluation of RSS Glenoid Component Loosening or Disassociation* The glenoid component is as resistant to loosening, disassociation of modular components, and dislocation as the predicate. 2. *Reverse Shoulder System Fatigue Test* The coating change has no effect on the implant fatigue strength. 3. *Evaluation of RSS Implant Titanium Plasma Spray Coating* The coating meets all acceptance criteria presented in the FDA documents "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis" and "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements".
Clinical Performance Data	Clinical performance data are not required to demonstrate substantial equivalence to the predicate device, as there have been no changes to fit, form, or function of the device.
Conclusions Drawn from Performance Data	The performance data demonstrate that the coating change does not raise any new issues regarding the safety or effectiveness of the TITAN Reverse Shoulder System, and the modified device is as safe and effective as the predicate.