DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 25, 2016

Integra LifeSciences Corporation
Mr. William Garzon
Senior Regulatory Affairs Specialist
8700 Cameron Road, Suite 100
Austin, Texas 78754

Re: K161189
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 5, 2016
Received: August 8, 2016

Dear William Garzon:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

INTEGRA® TITAN™ Reverse Shoulder System

Indications For Use:

The Titan Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previously 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.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Summary

807.92(a)(1) – Submitter Information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro NJ 08536
Name of Contact Person	William Garzon
Phone Number	(512) 596-8908
Fax Number	(512) 836-6933
Establishment Registration Number	1651501
Date Prepared	April 26, 2016
807.92(a)(2) – Name of device	
Trade or Propriety Name	INTEGRA® TITAN™ Reverse Shoulder System-Fracture Indications
Common or Usual Name	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Classification Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Panel	Orthopedic
Regulation	Class II (under 21CFR 888.3660)
Product Code	PHX
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
• Primary Predicate: Ascension® TITAN™ Reverse Shoulder System Glenoid (K130050) • Reference Device: Lima SMR Reverse Shoulder System (K110598) • Reference Device Tornier Aequalis Reversed Fracture (K112144)	
807.92(a)(4) - Device description The Integra TITAN Reverse Shoulder System is a semi-constrained modular total shoulder construct. The humeral components consist of humeral stems, varying heights of reverse bodies, 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 4 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.	
807.92(a)(5) – Intended Use of the device	
Indications for Use	The Titan Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previously 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.
807.92(a)(6) Comparison to Predicate Device(s)	
The INTEGRA® TITAN™ Reverse Shoulder System-fracture indications is the exactly the same as the predicate in terms of materials, form and function. No changes in technology or packaging have been made to the predicate device. Only the labeling has been changed to add the fracture indication.	
807.92(b)(1-2) – Nonclinical Tests Submitted	
No additional verification and validation test data were required as part of this submission. This 510(k) was submitted to expand the current INTEGRA® TITAN™ Reverse Shoulder System to include fracture indications. The Integra® TITAN™ Reverse Shoulder System cleaning validations for both sterile and non-sterile products incorporate endotoxin (LAL) testing that is performed in accordance with standards AAMI ST72 and United States Pharmacopeia (USP) Chapter <85>	
807.92(b)(3) – Conclusions drawn from non-clinical data Based upon the predicate comparison to design features, materials, and use, the INTEGRA® TITAN™ Reverse Shoulder System does not raise any new questions of safety or effectiveness to include a fracture indication to the current indications for use. In the original INTEGRA® TITAN™ Reverse Shoulder System 510(k) K130050 cleared on June 18, 2013, Integra has shown that the device is substantially equivalent to the Lima Corporate SMR Reverse Shoulder System that has a fracture indication.	