



Food and Drug Administration
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Silver Spring, MD 20993-0002

December 23, 2015

Integra LifeSciences Corporation
Mr. William Garzon
Senior Regulatory Affairs Specialist
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K152047

Trade/Device Name: INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: Class II

Product Code: KWS

Dated: November 24, 2015

Received: November 27, 2015

Dear Mr. 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 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.

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 yours,

Casey Hanley -S

Mark 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)
K152047

Device Name
INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid

Indications for Use (Describe)

The INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid is intended for use in Total Shoulder Arthroplasty which is indicated for:

1. Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicated that alternative methods of treatment are unsatisfactory.
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. – revision of a failed primary component)

The humeral component is intended for cemented or uncemented use.

The glenoid component is 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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Integra LifeSciences Corporation-Traditional 510(k)

INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid

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	December 22, 2015
807.92(a)(2) – Name of device	
Trade or Propriety Name	INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid
Common or Usual Name	Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Classification Name	Prostheses, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Classification Panel	Orthopedic
Regulation	Class II (under 21CFR 888.3660)
Product Code	KWS
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
<ul style="list-style-type: none"> • Ascension® TITAN™ Modular Total Shoulder System Glenoid (K100448) – Primary Predicate • DePuy Anchor Peg Glenoid (K052472) – Reference Device • Tornier Affiniti Glenoid (K103007) – Reference Device 	
807.92(a)(4) - Device description	
<p>The Integra TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid is a fully cemented all highly cross-linked polyethylene glenoid used in total shoulder arthroplasty for resurfacing the glenoid fossa. The glenoid component has one central peg with barbs and three peripheral pegs. The articulating surface of the glenoid device will be the same dimensions and sizes as existing Titan Modular Total Shoulder System three peg inline glenoids for consistent mismatching. The Fin-Lock™ Glenoid is intended to be a part of the TITAN™ Modular Shoulder System, 2.5 (K142413) and be used with the humeral component.</p>	
807.92(a)(5) – Intended Use of the device	
Indications for Use	<p>The INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid is intended for use in Total Shoulder Arthroplasty which is indicated for:</p> <ol style="list-style-type: none"> 1. Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis. 2. Fracture-dislocations of the proximal humerus where the

Integra LifeSciences Corporation-Traditional 510(k)

INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid

	<p>articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicated that alternative methods of treatment are unsatisfactory.</p> <p>3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. – revision of a failed primary component)</p> <p>The humeral component is intended for cemented or uncemented use.</p> <p>The glenoid component is intended for cemented use only.</p>
<p>807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate</p>	
<p>The INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid is similar in design and materials to the predicate device, Ascension® TITAN™ Modular Total Shoulder System (K100448). The INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid has similar indications for use, intended use and fundamental scientific technology as its predicate.</p> <p>The INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid is similar in central peg length to the predicate devices, DePuy Anchor Peg Glenoid (K052472) and Tornier Affiniti Glenoid (K103007).</p> <p>The differences between the predicates and proposed device do not raise any new issues regarding safety and effectiveness; therefore, the INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid is considered substantially equivalent to the predicate device.</p>	
<p>807.92(b)(1-2) – Nonclinical Tests Submitted</p>	
<p>Testing to verify the performance of the INTEGRA® TITAN™ Modular Total Shoulder System Fin-lock™ Glenoid included the following:</p> <ul style="list-style-type: none"> • Rocking and Subluxation Characterization Test • Glenoid Pull-out Fixation Test • Extensively Cross-Linked UHMWPE Material Characterization Test • Extensively Cross-Linked UHMWPE Wear Test <p>The results of these performance tests met their respective acceptance criteria and demonstrate that the INTEGRA® TITAN™ Modular Total Shoulder System Fin-Lock™ Glenoid is substantially equivalent to the predicate devices identified.</p>	
<p>807.92(b)(3) – Conclusions drawn from non-clinical data</p> <p>The design features, materials, intended use, and overall fundamental scientific technology of the INTEGRA® TITAN™ Modular Total Shoulder System are substantially equivalent to the predicate device. The safety and effectiveness of the INTEGRA® TITAN™ Modular Total Shoulder System is adequately supported by the substantial equivalence information, materials information, and performance data provided within this Premarket Notification submission.</p>	