DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 14, 2017

Ascension Orthopedics
Blesson Abraham
Senior Regulatory Affairs Specialist
8700 Cameron Road
Austin, Texas 78754

Re: K162153
Trade/Device Name: Integra® CAPTURE™ Screw System & Integra® Ti6® Internal Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 14, 2017
Received: June 15, 2017

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. 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" (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 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,

Vincent J. Devlin -S

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162153

Device Name
Integra® CAPTURE™ Screw System & Integra® Ti6® Internal Fixation System

Indications for Use *(Describe)*
The proposed indications for use for the Integra® CAPTURE™ Screw System are as follows:
"The CAPTURE™ Screw System implants (screws) are intended for fixation of fractures, non-unions, arthrodeses, and osteotomies of the small bones in the hand and foot. The implants are intended for single use only.

The proposed indications for use for the Integra® Ti6® Internal Fixation System are as follows:
"The Ti6® Internal Fixation System implants (screws) are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones in the hand and foot. The implants are intended for single 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Integra LifeSciences Corporation**
Traditional 510(k)
Integra® CAPTURE™ Screw System & Integra® Ti6® Internal Fixation System

# 510(k) Summary

**Sponsor:**
Ascension Orthopedics
8700 Cameron Road
Austin, TX 78754-3832, USA

**Contact Person:**
Blesson Abraham
Senior Regulatory Affairs Specialist
512-852-3942
512-368-1423

**Date:**
August 1, 2016

**Establishment Registration Number:**
1651501

**Trade Name:**
Integra® CAPTURE™ Screw System &
Integra® Ti6® Internal Fixation System

**Common Name:**
Bone Screw

**Product Code:**
HWC – Screw, Fixation, Bone

**Classification:**
21 CFR §888.3040 – Smooth or threaded metallic bone fixation fastener

**Classification Panel:**
Orthopedic

**Predicate Devices:**
Smith & Nephew, Inc. VLP Foot Plating, Screw System and Accessories, K090675, cleared on June 4, 2009.

Wright Medical Technology, Inc. WRIGHT™ Compression Screw, K082320, cleared on November 5, 2008.

Koby Surgical. Koby Surgical Internal Fixation System, K060026, cleared on January 26, 2006.

**Device Description:**
The Integra® CAPTURE™ Screw System and Integra® Ti6® Internal Fixation System consists of bone screws of various designs and sizes intended to fixate bones in cases of fractures, osteotomies, or fusions. The screws are self- drilling and self-tapping, and are manufactured from Ti-6Al-4V titanium alloy. This submission presents new cannulated (Digital Fusion) and non-cannulated (QuickSnap) screw designs that are line extensions to the current Integra® CAPTURE™ Screw System and Integra® Ti6® Internal Fixation System.

**Intended Use:**
The proposed indications for use for the Integra® CAPTURE™ Screw System are as follows:

"The CAPTURE™ Screw System implants (screws) are intended for fixation of fractures, non-unions, arthrodeses, and osteotomies of the small bones in the hand and foot. The implants are intended for single use only.

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|---|---|
| | The proposed indications for use for the Integra® Ti6® Internal Fixation System are as follows:<br>"The Ti6® Internal Fixation System implants (screws) are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones in the hand and foot. The implants are intended for single use only. |
| **Basis of Substantial Equivalence:** | The additional Integra® CAPTURE™ Screw System and Integra® Ti6® Internal Fixation System QuickSnap and Digital Fusion screws have the same intended use and fundamental scientific technology as the predicate devices. Sizing differences between the subject and predicate devices have been assessed and do not present new issues of safety or efficacy. Anodization surface treatment of the subject devices does not present new issues to safety or efficacy. Therefore, the proposed Integra® CAPTURE™ Screw System and Integra® Ti6® Internal Fixation System QuickSnap and Digital Fusion screws, anodization, are substantially equivalent to the predicate devices. |
| **Non-Clinical Performance Data:** | The following non-clinical performance analysis was conducted per ASTM F543 in order to establish substantial equivalence.<br>1. Torsional Strength<br>2. Driving Torque<br>3. Axial Pullout Strength<br>The Digital Fusion and QuickSnap performed substantially equivalent or better when compared to the predicate device. |
| **Clinical Performance Data:** | Clinical performance data was not necessary to demonstrate substantial equivalence. |