July 27, 2021

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

Re: K210016
Trade/Device Name: Integra DigiFuse Cannulated Intramedullary Fusion System,Integra Total Foot System,Integra CAPTURE Screw System & Integra Ti6 Internal Fixation System,Subtalar MBA System,MetaSurg Subtalar Implant,NewDeal BOLD Screw,NewDeal HALLU Lock Plate System,NewDeal HALLU Plates,QWIX Positioning Screw,SPIN Snap-Off Screw,NewDeal TIBIAXYS System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 18, 2021
Received: June 22, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210016

Device Name
Integra DigiFuse Cannulated Intramedullary Fusion System,Integra Total Foot System,Integra CAPTURE Screw System & Integra Ti6 Internal Fixation System,Subtalar MBA System,MetaSurg Subtalar Implant,NewDeal BOLD Screw,NewDeal HALLU Lock Plate System,NewDeal HALLU Plates,QWIX Positioning Screw,SPIN Snap-Off Screw,NewDeal TIBIAXYS System.

Indications for Use *(Describe)*
The DigiFuse® implant is indicated for the fixation
of osteotomies and reconstruction of the lesser
phalanges during procedures to correct deformities of the toes and fingers.
Indications include:
• Hammer toe deformity
• Claw toe deformity
• Mallet toe deformity
• Other deformities of the feet and hands
The DigiFuse® implants are intended for single use only.
Integra(r) total foot system is indicated for skeletally mature patients for the following:
-stabilization and fixation of fresh fractures
-intra and extra articular fractures, joint depression, and multi-fragmentary fractures
-revision procedures, joint fusion, and reconstruction of small bones of the feet.

The 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 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.

The Subtalar MBA System is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela.
*Severely pronated foot
*Walking intemperence
*Calcaneal stance position great than 5 degrees
*Manually correctable deformities
*Mid-tarsal breech (arch pain)
*Forefoot varus greater than 10 degrees

The metasurg subtalar implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and meical displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.
Indications include:
severe pronation
Calcaneal valgus deformity
plantarflexed talus
failed correction with long term orthotic treatment
congenital and painful flatfoot deformity
repair of tarsal coalitions
subtalar instability

posterior tibial tendon dysfunction
paralytic flat foot deformity
The metasurg subtalar implants are intended for single use only.

The "new" bold screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:
- fixation of small bone fragments, in long bones or small bones fractures.
- arthrodesis in hand or foot surgery
- mono or bi-cortical osteotomies in the foot or hand
- distal or proximal metatarsal or metacarpal osteotomies
- fixation of osteotomies for hallux valgus treatment (such as scarf, chevron, etc.)

The hallu lock plates are intended for fixation of fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint. Including cases of:
hallux rigidus
severe hallux valgus (im angle>20 degrees and hv angle >40 degrees)
deformity from rheumatoid arthritis
failed previous surgical procedures
traumatic arthritis
neuromuscular instability
the hallu lock plates must be fixed with the surfix fixed angle locking system and with the surfix-alpha variable angle locking system of 2.7mm or 3.0mm diameter (scews and lock-screws). Addition of a newdeal qwix screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.

The hallu plates are intended to be implanted for fixation of fractures, osteotomies or arthrodesis of the first metastarso-phalangeal joint, including cases of:
hallux rigidus
severe hallux valgus (im angle > 20 degree and hv angle >40 degree)
deformity from rheumatoid arthritis
failed previous surgical procedure
traumatic arthritis
neuromuscluar instability
The plates have to be fixed with the snap-off screws. Addition of a screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.

The qwix positioning screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:
* mono or bi-cortical osteotomies in the foot or hand (including hallux valgus treatment)
* fractures management in the foot or hand
* fixation of bone fragments in long bones or small bones fractures
*arthrodesis in hand, foot and ankle surgery
The size of the chosen screw should be adapted to the specific indication.

The "new" spin" snap-off screw is indicated for fixation of bone fractures of for bone reconstruction.
Examples include:
- fixation of small bone fragments
- weil osteomy
- mono-cortical fixation
- osteotomies and fractures fixation in the foot and hand.

The Newdeal TIBIAXYS System is indicated for fixation of bone fractures or for bone reconstruction including Arthrodesis, Osteotomies and fractures of ankle joint, distal tibia and fibula.
The Newdeal TIBIAXYS Plates have to be fixed with the SURFIX and SURFIX ALPHA 3.5mm diameter Locking System (screws and Lock screws).
Anterior plates for ankle Arthrodesis have to be fixed with the TIBIAXYS 4.0mm diameter cortical

screws.

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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510(k) Summary

Sponsor	Ascension Orthopedics, Inc. 11101 Metric Blvd. Austin, TX 78758
Establishment Number	3014207283
Point of Contact	Blesson Abraham 11101 Metric Blvd. Austin, TX 78758
Date	June 18, 2021
Trade Name	This 510(k) applies to multiple product lines, as identified below, as this is a bundled 510(k) per FDA Guidance Document, *Bundling Multiple Devices or Multiple Indications in a Single Submission.* **1.** Integra DigiFuse Cannulated Intramedullary Fusion System **2.** Integra Total Foot System **3.** Integra Capture Internal Fixation System & Integra Ti6 Internal Fixation System **4.** Subtalar MBA System **5.** MetaSurg Subtalar Implant **6.** NewDeal BOLD Screw **7.** New HALLU Lock Plate System **8.** NewDeal HALLU Plates **9.** QWIX Positioning Screw **10.** SPIN Snap-Off Screw **11.** NewDeal TIBIAXYS System
Common Name	**1.** Cannulated Intramedullary Fusion System **2.** Plate, Fixation, Bone **3.** Bone Screw **4.** Subtalar Arthrorisis Implant **5.** Subtalar Arthrorisis Implant **6.** Bone Fixation Screw, Cannulated Compression Screw **7.** Plate, Fixation, Bone **8.** Plate, Fixation, Bone **9.** Bone Fixation Screw **10.** Bone Fixation Screw, Self-Drilling and Self-Tapping Snap-Off Screw **11.** Plate, Fixation, Bone
Classification Name	**1.** HWC – Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) **2.** HRS – Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) **3.** HWC – Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) **4.** HWC – Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) **5.** HWC – Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) **6.** HWC – Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) **7.** HRS – Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) **8.** HRS – Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) **9.** HWC – Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

	10. HWC – Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) **11.** HRS – Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Classification	Class II
Predicate Device	Primary Predicate **1.** K152527 – Integra DigiFuse Cannulated Intramedullary Fusion System Additional predicates are as follows and identified with the corresponding reference from the previous sections of this 510(k) summary. **2.** K123000 – Integra Total Foot System **3.** K162153 – Integra Capture Internal Fixation System & Integra Ti6 Internal Fixation System **4.** K960692 – Subtalar MBA System **5.** K111265 – MetaSurg Subtalar Implant **6.** K011262 – NewDeal BOLD Screw **7.** K083154 – NewDeal HALLU Lock Plate System **8.** K093781 – NewDeal HALLU Plates **9.** K071639 – QWIX Positioning Screw **10.** K011946 – SPIN Snap-Off Screw **11.** K073375 – NewDeal TIBIAXYS System
Classification Panel	Orthopedic
Device Description	The purpose of this submission is the addition of MR Conditional information to the labeling for the predicate devices. The addition of MR labeling to the subject devices does not impact indications, materials, design features or dimensions, packaging or sterilization.
Intended Use/ Indications for Use	The intended use/indications for use of the predicate devices identified remain the same as previously cleared in their respective 510(k)s. The respective 510(k)s for the devices can be referenced in the predicate device section above.
Nonclinical Performance Data	Non-clinical Magnetic Resonance Imaging (MRI) testing performed on the devices determined the devices are MR conditional in accordance with ASTM F2503 (Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment) and FDA Guidance (Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment). MR Testing addressed the following: 1. Magnetically Induced Displacement Force (ASTM F2052) 2. Magnetically Induced Toque (ASTM F2213) 3. RF-induced heating (ASTM F2182) 4. Image Artifact (ASTM F2119)
Conclusion	The completed MR compatibility testing establishes the conditional safety and compatibility of the passive implant devices in the MR environment, and the addition of MR Conditional labeling.