



September 23, 2020

Integrity Implants Inc.
Ms. Lauren Kamer
Senior Director of Regulatory and Clinical Affairs
354 Hiatt Drive
Palm Beach Gardens, Florida 33418

Re: K201367

Trade/Device Name: FlareHawk® Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 18, 2020
Received: August 20, 2020

Dear Ms. Kamer:

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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K201367

Device Name

FlareHawk Interbody Fusion System

Indications for Use (Describe)

The FlareHawk Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

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 - K201367

FlareHawk Interbody Fusion System

AUGUST 18, 2020

- I. Company:** Integrity Implants Inc.
354 Hiatt Drive
Palm Beach Gardens, FL 33418
Telephone: 561-529-3861
- II. Contact:** Lauren Kamer
Senior Director of Regulatory and Clinical Affairs
- III. Proprietary Trade Name:** FlareHawk® Interbody Fusion System
- IV. Common Name:** Intervertebral Body Fusion Device
with Bone Graft, Lumbar
- V. Classification Name:** Intervertebral Body Fusion Device (21 CFR 888.3080)
Class: II
Product Code: MAX

VI. Product Description

Integrity Implants' FlareHawk Interbody Fusion System is an expandable lumbar intervertebral body fusion device intended for use in the lumbosacral spine from L2 to S1. The FlareHawk interbody fusion device consists of a shell and a shim component that are offered in various lengths, heights, and lordotic angles to accommodate variations in patient anatomy. When the FlareHawk device is deployed within the intervertebral disc space, the shell and shim components lock together to create a complete implant construct to provide structural stability for interbody fusion. The final dimensions of the deployed device construct are determined by the dimensions of the selected shell and shim. Once implanted via a transforaminal (TLIF) or posterior (PLIF) approach, the FlareHawk interbody fusion device is designed to restore intervertebral disc height, provide anterior column support, and maintain structural stability of the motion segment

to facilitate intervertebral body fusion. The FlareHawk interbody fusion device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone, and with supplemental fixation instrumentation that has been cleared for use in the lumbar spine. The FlareHawk Interbody Fusion System includes manual surgical instruments for delivery of the implant device and for disc preparation. FlareHawk Interbody Fusion System implant and instrument devices are supplied non-sterile and are intended for steam sterilization by the user prior to use.

VII. Indications for Use

FlareHawk Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

VIII. Summary of Technological Characteristics

The subject FlareHawk Interbody Fusion System has substantially similar fundamental scientific technology as the predicate FlareHawk Interbody Fusion System.

Like the predicate FlareHawk Interbody Fusion System, the shell component of the subject FlareHawk Interbody Fusion System implants is a rectangular frame that is inserted into the disc space in a non-expanded form, with subsequent in-situ expansion resulting from the insertion of the shim component. The shell component is manufactured from PEEK per ASTM F2026, and incorporates an integrated core manufactured from titanium alloy per ASTM F136, and tantalum markers per ASTM F560 for imaging purposes. The shell component features a bulleted nose designed to facilitate ease of insertion, as well as directional teeth on its superior and inferior surfaces to resist expulsion. Like the

predicate FlareHawk Interbody Fusion System, the shim component of the subject FlareHawk Interbody Fusion System implants has a tapered front end that inserts into and expands the shell component to the desired height and lordosis. The shim is manufactured from titanium alloy per ASTM F136 and the shims are color anodized by size. The shim locks to both the shell core and the posterior of the shell when the implant is deployed.

The subject FlareHawk Interbody Fusion System shell components are coated with Grade 2 commercially pure titanium that meets the chemical composition requirements of ASTM F67.

IX. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence

To demonstrate the substantial equivalence of the subject FlareHawk Interbody Fusion System to legally marketed predicate devices, FlareHawk Interbody Fusion System, K182114 (SE 01/07/2019), is used as the primary predicate device. Integrity Implants' FlareHawk Interbody Fusion System, K183184 (SE 04/03/2019), is also used as a predicate for this submission.

Additionally, the following devices are being used as additional predicate devices for this submission to demonstrate that commercially pure titanium coatings are not new and currently exist on other legally marketed lumbar interbody fusion devices:

- SpineFrontier Lumbar Interbody Fusion Device System (K142504, SE 05/13/2015)
- Tyber Medical Intervertebral Body Fusion Device (K130573, SE 09/30/2013)
- Alphatec Spine Battalion Universal Spacer System (K143740, SE 05/22/2015)
- Octane Straight Intervertebral Fusion Device, Ti Coated (K150152, SE 05/11/2015)

X. Brief Discussion of the Non-Clinical and Clinical Tests Submitted

Integrity Implants has conducted bench performance testing in support of this premarket notification submission as follows:

- Coating Characterization and Coating Integrity Testing
 - Stereological Assessment in accordance with ASTM F1854 (as appropriate)
 - Static Shear Strength in accordance with ASTM F1044

- Static Tensile Strength in accordance with ASTM F1147
- Abrasion Resistance in accordance with ASTM F1978
- Wear Debris and Particle Characterization in accordance with ASTM F1877
- Finished Device Mechanical Testing
 - Static Axial Compression in accordance with ASTM F2077
 - Dynamic Axial Compression in accordance with ASTM F2077
 - Static Compression Shear in accordance with ASTM F2077
 - Dynamic Compression Shear in accordance with ASTM F2077

Integrity Implants has conducted a biocompatibility assessment in accordance with ISO 10993-1, including cytotoxicity testing in accordance with ISO 10993-5.

XI. Conclusions Drawn for the Non-Clinical and Clinical Tests

Based on the bench performance testing, biocompatibility assessment/testing, and other supporting documentation provided in this premarket notification, the subject FlareHawk Interbody Fusion System demonstrates substantial equivalence to legally marketed predicate devices, and any differences between the subject device and the predicate devices do not impact the safety and effectiveness of FlareHawk Interbody Fusion System.