May 21, 2025

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

Re: K243116
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: April 24, 2025
Received: April 24, 2025

Dear Lauren 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243116

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

FlareHawk® Interbody Fusion System

April 24, 2025

I.	**Company:**	Integrity Implants Inc. dba Accelus 354 Hiatt Drive Palm Beach Gardens, FL 33418 Telephone: 561-529-3861
II.	**Contact:**	Lauren Kamer Regulatory Affairs Consultant
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

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, 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.

VII. Indications for Use

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.

VIII. Summary of Technological Characteristics

The subject FlareHawk Interbody Fusion System has the identical 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 shim locks to both the shell core and the posterior of the shell when the implant is deployed.

Like the predicate FlareHawk Interbody Fusion System, the subject 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 subject shell components are offered in both non-coated and coated with CP titanium (Grade 2 commercially pure titanium that meets the chemical composition requirements of ASTM F67) versions. 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 are color anodized for differentiation.

Like the predicate FlareHawk Interbody Fusion System, the subject shells and shims are offered in both non-sterile (and intended to be steam sterilized by the user) and gamma sterilized versions.

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 K202198 (SE 11/03/2020) is used as the primary predicate device. Integrity Implants' FlareHawk Interbody Fusion System K220453 (SE 03/24/2022) is also used as a predicate for this submission.

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

Bench performance testing conducted in support of this premarket notification submission included an evaluation of magnetic field interactions, artifacts, and radio frequency induced heating in accordance with the following standards:

- ASTM F2052 *Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment*

- ASTM F2213 *Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment*
- ASTM F2119 *Standard test method for evaluation of MR image artifacts from passive implants*
- ASTM F2182 *Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging*

In addition to bench performance testing, validated modeling studies were conducted to confirm the worst case device configuration for MR induced heating, as well as to assess worst case in-vivo heating in clinically-relevant muscle-like and bone tissues.

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

Based on the MRI safety testing, modeling studies, and other supporting documentation provided in this premarket notification, the subject FlareHawk Interbody Fusion System demonstrates substantial equivalence to legally marketed predicate devices, including the previously cleared FlareHawk Interbody Fusion System.