March 25, 2022

Integrity Implants Inc.
Ms. Alexa Kamer
Associate Regulatory Affairs Specialist
354 Hiatt Drive
Palm Beach Gardens, Florida 33418

Re: K213355
Trade/Device Name: Toro-L Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: February 18, 2022
Received: February 22, 2022

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 L. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213355

Device Name

Toro-L Interbody Fusion System

Indications for Use *(Describe)*

The Toro-L Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortical cancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems (e.g., pedicle screw/rod systems) cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Toro-L Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Toro-L Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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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K213355

Toro-L Interbody Fusion System

510(k) SUMMARY

October 08, 2021

I. Company:

Integrity Implants Inc.
354 Hiatt Drive
Palm Beach Gardens, FL 33418
Telephone: 561-529-3861

II. Contact:

Alexa Kamer
Associate Regulatory Affairs Specialist

III. Proprietary Trade Name: Toro-L® Interbody Fusion System

IV. Common Name: Intervertebral Body Fusion Device with Bone Graft, Lumbar; Intervertebral Body Fusion Device with Bone Graft, Thoracic

V. Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)
Class: II
Product Code: MAX, PHM

VI. Product Description

Integrity Implants' Toro-L Interbody Fusion System incorporates a bi-directional expandable interbody fusion device and a non-expandable monolithic interbody fusion device intended for use in the thoracolumbar spine from T1-S1. The Toro-L Interbody Fusion System implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136 and Ti-6Al-4V per ASTM F2924) and polyether ether ketone (PEEK) per ASTM F2026; and are offered in a range of sizes and lordotic options to accommodate variations in patient anatomy.

Once implanted via a lateral surgical approach, the Toro-L interbody fusion devices are designed to restore intervertebral disc height, provide anterior column support, and maintain structural stability of the motion segment to facilitate intervertebral body fusion. The Toro-L interbody fusion devices interbody fusion device is intended to be used with autograft and/or allograft, and with supplemental fixation instrumentation that has been cleared for use in the thoracolumbar spine. The Toro-L interbody fusion devices are single use devices. The Toro-L Interbody Fusion System includes manual surgical instruments for delivery of the implant devices and for disc preparation. The Toro-L 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

The Toro-L Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortical cancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems (e.g., pedicle screw/rod systems) cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Toro-L Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Toro-L Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

VIII. Summary of Technological Characteristics

The subject Toro-L Interbody Fusion System implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136 and Ti-6Al-4V per ASTM F2924) and polyether ether ketone (PEEK) per ASTM F2026; and are offered in a range of sizes and lordotic options to accommodate variations in patient anatomy.

The Toro-L Interbody Fusion System expandable implant has integrated ramps that allow the implant to be inserted in a non-expanded form, and then subsequently expanded to full width and desired height through continuous expansion. When the desired implant height is achieved, the locking system is engaged to secure the construct in its final expanded configuration. The implant is then post-packed with bone graft. The design includes a bullet-nosed tip to aid in insertion into the disc space, and teeth on the superior and inferior surfaces to resist expulsion.

The monolithic implant is a non-expanding conventional spacer with the interior space of the device divided into two compartments for bone graft containment.

Both the expandable and monolithic configurations have protrusions on the superior and inferior surfaces of the endplates of the implant to grip the adjacent vertebral endplates to resist expulsion.

The subject implant and instruments are offered non-sterile and are intended to be steam sterilized by the user prior to use.

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, Toro-L Interbody Fusion System, K203038 (SE 03/26/2021), is used as the primary predicate device. Integrity Implants' FlareHawk Interbody Fusion System, K183184 (SE 04/03/2019), is additionally used as a predicate for this submission

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:

- 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

Additionally, Integrity Implants has conducted a biocompatibility assessment in accordance with ISO 10993-1.

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

Based on the bench performance testing, biocompatibility assessment, and other supporting documentation provided in this premarket notification, the subject Toro-L Interbody Fusion System demonstrates substantial equivalence to legally marketed predicate devices including the previously cleared Toro-L Interbody Fusion System.