September 10, 2020

Expanding Innovations, Inc.
% Ms. Nancy Lincé
Regulatory Affairs Consultant
Lincé Consulting, LLC
111 Deerwood Road, Suite 200
San Ramon, California 95483

Re: K201145
Trade/Device Name: X-Pac Expandable Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 7, 2020
Received: August 10, 2020

Dear Ms. Lincé:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201145

Device Name
Expanding Innovations X-Pac Expandable Lumbar Cage System

Indications for Use *(Describe)*
The Expanding Innovations X-Pac Expandable Lumbar Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients. The system is designed for use with autogenous bone graft material to facilitate spinal fusion.

The system is intended for use in patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have at least 6 months of non-operative treatment prior to surgery. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via transforaminal approach using autogenous bone graft material. The system is intended for use with supplemental fixation systems cleared for use by the FDA for use in the thoracolumbar 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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, and Phone Number of Applicant

Expanding Innovations, Inc.
110 Pioneer Way, Suite I
Mountain View, CA 94041
Phone: (650) 861-3129

B. Contact Person

Nancy Lincé
Regulatory Affairs Consultant
Lincé Consulting, LLC

C. Date Prepared

August 7, 2020

D. Device Name and Classification

Trade Name:	Expanding Innovations X-Pac Expandable Lumbar Cage System
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device-Lumbar
Regulation #:	21 CFR§888.3080
Product Code:	MAX

E. Primary Predicate Device

The Expanding Innovations X-Pac Expandable Lumbar Cage System is substantially equivalent to the previously cleared X-Pac Expandable Lumbar Cage System, K152539 and K160856.

F. Additional Predicate Device

Titan Spine Inc., Endoskeleton TT, K083714

G. Device Description

The X-Pac Expandable Lumbar Cage System is a lumbar interbody fusion system comprised of a cage implant and surgical instruments. The implants are used to provide structural stability in skeletally mature individuals following discectomy and

are placed via the transforaminal approach. The device is available in different sizes and footprints, to accommodate varying patient anatomy, and is designed to allow for intraoperative adjustment in both the parallel and lordotic configurations. The implants are designed for use with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each implant grip the endplates of the adjacent vertebrae to resist expulsion. The implants are manufactured from medical grade titanium alloy per ASTM F136 and ASTM F1295. The Expanding Innovations X-Pac Expandable Lumbar Cage System implants are single-use, provided non-sterile, and are intended to be cleaned and steam sterilized before use. The surgical instruments are re-usable, provided non-sterile, and are intended to be cleaned and steam sterilized before each use. Additional cage sizes are the subject of this Special 510(k).

H. Indications for Use / Intended Use

The Expanding Innovations X-Pac Expandable Lumbar Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients. The system is designed for use with autogenous bone graft material to facilitate spinal fusion.

The system is intended for use in patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have at least 6 months of non-operative treatment prior to surgery. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via transforaminal approach using autogenous bone graft material. The system is intended for use with supplemental fixation systems cleared for use by the FDA for use in the thoracolumbar spine.

I. Technological Comparison

The technological characteristics of the Expanding Innovations X-Pac Expandable Lumbar Cage System implants are substantially equivalent to the predicate in terms of intended use, indications for use, overall design, function, technology, materials, and performance.

J. Performance Data

A risk assessment, including mechanical testing, was conducted to confirm that the new cage sizes not introduce new issues of safety or effectiveness. The new cage sizes successfully underwent performance testing including verification and validation testing and mechanical testing in accordance with ASTM F2077 for compression and compressive shear paradigms; ASTM F2267 for subsidence testing; and expulsion testing. The mechanical performance tests were based on well-recognized test methods for interbody fusion devices, including those outlined in *Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*. Test results demonstrate substantial equivalence to the predicate device.

K. Basis for Substantial Equivalence

The modified X-Pac Expandable Lumbar Cage System is identical to the predicate with respect to intended use, indications for use, overall design, function, technology, materials, and performance as well as procedural steps, surgical instrumentation, and product labeling. The information provided supports the substantial equivalence of the modified X-Pac Expandable Lumbar Cage System to the legally marketed predicate devices.