February 14, 2023

Expanding Innovations, Inc.
% Carolyn Guthrie
VP of QA/RA
Kapstone Medical, LLC.
510 Elliot Street
Charlotte, North Carolina 28202

Re: K223174
Trade/Device Name: X-Pac Expandable LLIF Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 12, 2023
Received: January 13, 2023

Dear Carolyn Guthrie:

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

510(k) Number *(if known)*

K223174

Device Name

X-Pac Expandable LLIF Cage System

Indications for Use *(Describe)*

The Expanding Innovations X-Pac Expandable LLIF Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. The X-Pac Expandable LLIF Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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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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, Phone, and Fax Number of Applicant

Expanding Innovations, Inc.
110 Pioneer Way, Suite 1
Mountain View, CA 94041
Phone: (925)-819-2257

B. Contact Person

Carolyn Guthrie
Vice President, Regulatory Affairs
Kapstone Medical, LLC

C. Date Prepared

November 9, 2022

D. Device Name and Classification

Trade Name:	X-Pac Expandable LLIF Cage System
Common Name:	Intervertebral Body Fusion Device
CFR Classification:	21 CFR§888.3080
Classification Name:	Intervertebral Body Fusion Device
Product Code:	MAX

E. Predicate Device

The Expanding Innovations X-Pac Expandable LLIF Cage System is substantially equivalent to the previously cleared Zavation eZspand Interbody System (K220581).

F. Device Description

The Expanding Innovations X-Pac Expandable LLIF 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 lateral approach. The device is available in various sizes and footprints to accommodate varying anatomy, and is designed to allow for intraoperative adjustment. 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 F1472. The Expanding Innovations X-Pac Expandable LLIF 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.

G. Indications for Use / Intended Use

The Expanding Innovations X-Pac Expandable LLIF Cages are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft. X-Pac Expandable LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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H. Technological Comparison

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

I. Performance Data

Mechanical testing was conducted to confirm that the Expanding Innovations X-Pac Expandable LLIF Cage System does not introduce new issues of safety or effectiveness. The LLIF Cage System successfully underwent performance testing including mechanical testing in accordance with ASTM F2077 for compression and compressive shear paradigms. 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.

J. Basis for Substantial Equivalence

The Expanding Innovations X-Pac Expandable LLIF Cage System is identical to the predicate with respect to intended use, indications for use, overall design, function, technology, materials, and performance. The information provided supports the substantial equivalence of the modified X-Pac Expandable LLIF Cage System to the legally marketed predicate devices.