June 25, 2025

Expanding Innovations, Inc
℅ Carolyn Guthrie
Principal Consultant
Helix Medical, LLC
711 SE 5th Avenue
Pompano Beach, Florida 33060

Re: K251003
Trade/Device Name: X-PAC® LLIF Expandable Lateral Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 25, 2025
Received: April 28, 2025

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

510(k) Number *(if known)*
K251003

Device Name
X-PAC® LLIF Expandable Lateral Cage System

Indications for Use *(Describe)*
X-PAC® LLIF Expandable Lateral 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 intended to be used with autograft and/or allograft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. X-PAC® LLIF Expandable Lateral 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.

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

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510(k) Summary

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

A. Name, Address, Phone Number of Applicant

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

B. Contact Person

Carolyn Guthrie
Principal Consultant
Helix Medical, LLC
Phone: (704)-737-2866

C. Date Prepared

June 23, 2025

D. Device Name

Trade Name:	X-PAC® LLIF Expandable Lateral Cage System
Common Name:	Intervertebral body fusion device
CFR Classification:	21 CFR §888.3080
Classification Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Product Code:	MAX

E. Predicate Device(s)

Predicate #	Predicate Trade Name	Product Code
K223174	X-PAC Expandable LLIF Cage System	MAX

F. Device Description Summary

X-PAC® LLIF Expandable Lateral 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 the devices that are the subject of this 510(k) are placed via a lateral approach. The device is available in various sizes and footprints to accommodate varying anatomy and is designed to allow for intraoperative adjustment in the height of the cage. Surfaces of the upper plate and bottom housing that contact the vertebral endplates are “toothed” to provide stability within the intervertebral space. The outer surface teeth are designed to resist expulsion in all directions. The fenestrated cage contains openings to enhance bony ingrowth and has a bulleted nose for easier entry into the disc space. The implants are manufactured from medical grade titanium alloy per ASTM F136, and ASTM F1472. X-PAC® LLIF Expandable Lateral Cage System implants are single-use, provided non-sterile, and are intended to be steam sterilized before use. The surgical instruments are designed to facilitate precise placement of the device within the intervertebral disc body, and are re-usable, provided non-sterile, and are intended to be cleaned and steam sterilized before each use.

G. Intended Use / Indications for Use

X-PAC® LLIF Expandable Lateral 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 intended to be used with autograft and/or allograft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. X-PAC® LLIF Expandable Lateral 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.

H. Indications for Use Comparison

The indications for use of the subject device and the predicate device are similar.

I. Technological Comparison

The subject and predicate cages are designed to provide scaffolding within a disc space that distracts and supports the opposing discs and promotes endplate-to-endplate fusion in the lumbar spine. The subject and predicate cages are identical in their intended use and identical in materials, manufacturing, operating parameters and instrumentation used to facilitate placement. Implantation of the modified and predicate cage models is performed using identical techniques and instruments.

Non-clinical testing was conducted to demonstrate that the device meets the product specifications, pertinent standards (ASTM F2077), and the product labeling.

J. Non-Clinical and/or Clinical Tests Summary & Conclusions

The X-PAC® LLIF Expandable Lumbar Cage System successfully underwent the following performance testing:

- ASTM F2077-22 Standard Test Methods for Intervertebral Body Fusion Devices
  - Static and dynamic axial compression
  - Static and dynamic compression shear
  - Expulsion & Subsidence Testing (ASTM 2267)
  - Wear Analysis

The mechanical performance tests were based on well-recognized test methods for interbody fusion devices, including those outlined in Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.

The non-clinical testing, when compared to the predicate data, demonstrated equivalent or superior mechanical performance and fatigue testing.