May 20, 2025

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

Re: K250602
Trade/Device Name: X-PAC® N-GAGE™ Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ, OVD
Dated: February 27, 2025
Received: February 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,

Maziar Shah Mohammadi

For: 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)*
K250602

Device Name
X-PAC® N-GAGE™ Lumbar Plate System

Indications for Use *(Describe)*

X-PAC® N-GAGE™ Lumbar Plate System:
X-PAC® N-GAGE™ 2-Hole and 4-Hole Lumbar Plate System is indicated for temporary stabilization during spinal fusion via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via a lateral or anterolateral surgical approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability in skeletally mature patients for the treatment of degenerative disc disease (DDD), spondylolisthesis, spondylolysis, spinal stenosis, pseudoarthrosis, deformity (defined as scoliosis, kyphosis, or lordosis), tumors, trauma (i.e. fractures including dislocation and subluxation), and/or failed previous fusion. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

X-PAC® Plate-Cage System:
N-GAGE™ 2-Hole and 4-Hole Plates may be assembled with the X-PAC® LLIF Expandable Cage to create a plate-spacer assembly. When assembled to the X-PAC® LLIF Expandable Cage, the plate-spacer assembly is indicated for standalone use at one or two levels of the lumbosacral spine (L2-S1), as an adjunct to fusion in skeletally mature patient with degenerative disc disease (DDD). DDD is defined as discogenic back pain with degeneration of the disc confirmed by 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. Patients should have at least six (6) months of non-operative treatment.

N-GAGE™ 1-Hole Plate is to be assembled with the X-PAC® LLIF Expandable Cages. When assembled, the system is intended to maintain the relative position of X-PAC® LLIF Expandable Cage and intended for use with supplemental fixation (e.g., posterior spinal systems).

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, and Fax 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

May 12, 2025

D. Device Name

Trade Name:	X-PAC® N-GAGE™ Lumbar Plate System
Common Name:	Appliance, Fixation, Spinal Intervertebral body; Intervertebral Fusion Device With Integrated Fixation, Lumbar
CFR Classification:	21 CFR §888.3060; 21 CFR §888.3080
Classification Name:	Spinal Intervertebral Body Fixation Orthosis; Interbody Fusion Device
Product Code:	KWQ, OVD

E. Predicate Device(s)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200885	SeaSpine Regatta Lateral Plate System	KWQ
K200879	SeaSpine Regatta Lateral System	MAX, OVD
K223174	Expanding Innovations X-Pac Expandable LLIF Cage System	MAX

F. Device Description Summary

X-PAC® N-GAGE™ Lumbar Plate System is a lumbar plate system comprised of implants (plates and screws), couplers, and surgical instruments. The implants are used in a lateral approach interbody fusion and are designed to provide rigid stabilization and support to the spinal column. The plate helps to restrict movement between adjacent vertebrae, preventing further injury and promoting the fusion of the bones over time. During operation, the plate is positioned laterally or anterolaterally, following insertion of a spinal interbody fusion spacer, via a removable inserter and screwdriver. The plate system can be installed either attached to (with a coupler) or floating from the X-PAC® LLIF Cage. The plates are available in multiple sizes and configurations to accommodate all heights of interbody spacing. The plates have a flat, elongated shape that conforms to the curvature of the spine at the required level(s) and have holes to secure the plate to the vertebrae. The fully threaded screws are available in two diameters and multiple lengths to accommodate varying anatomies. The screws are inserted into the vertebral body to hold the plate in place. The system includes a 1-hole, 2-hole, and 4-hole configuration. The screw can be angled up to 20 degrees away from the cage, and 10 degrees towards the cage. Each screw hole has an adjacent tab, which is turned and locked over the screw head once the screw has been inserted. The coupler is used to create a secure connection between the plate and the interbody device. The plates, screws, tabs, and couplers are manufactured from medical grade titanium alloy per ASTM F136.

G. Intended Use / Indications for Use

<u>X-PAC® N-GAGE™ Lumbar Plate System:</u>

X-PAC® N-GAGE™ 2-Hole and 4-Hole Lumbar Plate System is indicated for temporary stabilization during spinal fusion via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via a lateral or anterolateral surgical approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability in skeletally mature patients for the treatment of degenerative disc disease (DDD), spondylolisthesis, spondylolysis, spinal stenosis, pseudoarthrosis, deformity (defined as scoliosis, kyphosis, or lordosis), tumors, trauma (i.e. fractures including dislocation and subluxation), and/or failed

previous fusion. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

X-PAC® N-GAGE™ Plate-Cage System:

N-GAGE™ 2-Hole and 4-Hole Plates may be assembled with the X-PAC® LLIF Expandable Cage to create a plate-spacer assembly. When assembled to the X-PAC® LLIF Expandable Cage, the plate-spacer assembly is indicated for standalone use at one or two levels of the lumbosacral spine (L2-S1), as an adjunct to fusion in skeletally mature patient with degenerative disc disease (DDD). DDD is defined as discogenic back pain with degeneration of the disc confirmed by 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. Patients should have at least six (6) months of non-operative treatment.

N-GAGE™ 1-Hole Plate is to be assembled with the X-PAC® LLIF Expandable Cages. When assembled, the system is intended to maintain the relative position of X-PAC® LLIF Expandable Cage and intended for use with supplemental fixation (e.g., posterior spinal systems).

H. Indications for Use Comparison

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

I. Technological Comparison

The technological characteristics of the subject and the predicate device were identified and compared, including materials, design, and principles of operation. The mechanisms of action for X-PAC® N-GAGE™ Lumbar Plate System with and without integrated fixation are equivalent to that of the SeaSpine Regatta Lateral System. Each system consists of plates and screws and are made from the same material. Differences in technological characteristics are not expected to affect performance and safety.

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

The X-PAC® N-GAGE™ Lumbar Plate System successfully underwent the following performance testing:

- ASTM F1717-21: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
  - static and dynamic compression bending
  - static torsion
- Retention Feature Strength / Screw Pushout Testing
- ASTM F543-23: Standard Specification and Test Methods for Metallic Medical Bone Screws
  - Torsion
  - Driving torque
  - Axial pullout
- ASTM F2077-22 Standard Test Methods for Intervertebral Body Fusion Devices
  - Static and dynamic axial compression
  - Static and dynamic compression shear

The X-PAC® N-GAGE™ Lumbar Plate System is substantially equivalent to legally marketed predicates with respect to indications, design, materials, function, operation, and performance.