February 13, 2026

NanoHive Medical, LLC
% Hannah Taggart
Engineer & Regulatory Specialist
Applied Technical Services (Empirical Technologies)
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K254105
Trade/Device Name: Hive™ Standalone Cervical System and Hive™ C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: December 18, 2025
Received: December 19, 2025

Dear Hannah Taggart:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

KATHERINE D.
KAVLOCK -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254105

Device Name
Hive™ Standalone Cervical System and Hive™ C Interbody System

Indications for Use *(Describe)*
The Hive™ Standalone Cervical System, including devices with a microscopic roughened surface and micro and nano-scale features, is indicated at one or more levels of the cervical spine (C2-T1) in skeletally mature patients with cervical degenerative disc disease (DDD), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six (6) weeks of non-operative treatment prior to treatment with the devices. The device is indicated to be used with autograft bone and/or allograft bone comprised of cancellous, cortical, and/or corticocancellous bone.

The Hive™ Standalone Cervical System is intended to be used with screws or anchors. When used with two screws, these devices are stand-alone interbody fusion devices. When used with anchors, or without two screws, these devices are intended to be used with supplemental fixation (e.g. cervical plates or cervical posterior fixation).

The Hive™ C Interbody System, including devices with a microscopic roughened surface and micro and nano-scale features, is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. Patients should have received at least six (6) weeks of non-operative treatment prior to treatment with an interbody fusion device. The Hive™ C Interbody System is indicated to be used with autograft bone and/or allograft bone comprised of cancellous, cortical, and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion (hereafter referred to as bone graft). The Hive™ C Interbody System requires additional supplemental fixation cleared for use in the cervical 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.

510(K) SUMMARY

Submitter's Name:	NanoHive Medical LLC
Submitter's Address:	12 Gill Street, Suite 4500 Woburn, MA 01801
Submitter's Telephone:	1-844-943-5433
Contact Person:	Hannah Taggart, MS Applied Technical Services (Empirical Technologies) 719- 457-1152 htaggart@atslab.com
Date Summary was Prepared:	December 18, 2025
Trade or Proprietary Name:	Hive™ Standalone Cervical System and Hive™ C Interbody System
Device Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical Intervertebral Fusion Device with Bone Graft, Cervical
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	OVE, ODP
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Hive™ Standalone Cervical System consists of additively manufactured interbody fusion cages made from Ti-6Al-4V per ASTM F3001 and screws, plates, and anchors made from Ti-6Al-4V per ASTM F136. The cages, bone screws, and plates were originally cleared via K223190. The purpose of this submission is to add bone anchors as an additional form of internal fixation and include an additional packaging configuration option. The implant components of the Hive™ Standalone Cervical System are offered in a variety of sizes to accommodate patient anatomy and surgical approach. The cage implants are provided sterile while the bone screws and anchors are provided non-sterile.

The Hive™ C Interbody System consists of interbody fusion cages additively manufactured from Ti-6Al-4V ELI per ASTM F001. The interbody cages have a microscopic-roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

The Hive™ C Interbody System implants are offered in a variety of lengths, widths and cross sectional geometries to accommodate patient anatomy and surgical approach. The implants are provided sterile. The purpose of this submission is to modify the indications for use and packaging from the previously cleared system.

INDICATIONS FOR USE

Hive™ Standalone Cervical System

The Hive™ Standalone Cervical System, including devices with a microscopic roughened surface and micro and nano-scale features, is indicated at one or more levels of the cervical spine (C2-T1) in skeletally mature patients with cervical degenerative disc disease (DDD), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six (6) weeks of non-operative treatment prior to treatment with the devices. The device is indicated to be used with autograft bone and/or allograft bone comprised of cancellous, cortical, and/or corticocancellous bone.

The Hive™ Standalone Cervical System is intended to be used with screws or anchors. When used with two screws, these devices are stand-alone interbody fusion devices. When used with anchors, or without two screws, these devices are intended to be used with supplemental fixation (e.g. cervical plates or cervical posterior fixation).

Hive™ C Interbody System

The Hive™ C Interbody System, including devices with a microscopic roughened surface and micro and nano-scale features, is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. Patients should have received at least six (6) weeks of non-operative treatment prior to treatment with an interbody fusion device. The Hive™ C Interbody System is indicated to be used with autograft bone and/or allograft bone comprised of cancellous, cortical, and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion (hereafter referred to as bone graft). The Hive™ C Interbody System requires additional supplemental fixation cleared for use in the cervical spine.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Structure and Function
- Materials of manufacture
- Sterility
- Sizes
- Integrated Fixation methods
- Manufacturing and Biocompatibility

Predicate Devices – Hive™ Standalone Cervical System

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K223190	Hive™ Standalone Cervical System	NanoHive Medical LLC	OVE, ODP	Primary
K241846	E3D™-C Interbody System	Evolution Spine	OVE, ODP	Additional

The subject device is different from the predicate devices in the following ways:

- Anchor Diameter: The subject device offers anchors with a different diameter than the predicate. The subject anchors were evaluated in cantilever bending testing per ASTM F2193 and shown to be substantially equivalent to a predicate bone screw. Therefore, this difference does not raise any concerns for the safety and efficacy of the subject system.

There are no differences between the subject and predicate devices which raise questions for the safety and efficacy of the subject devices.

Predicate Devices – Hive™ C Interbody System

510k Number	Trade or Proprietary Name	Manufacturer	Predicate Type
K180364	HD LifeSciences Cervical IBFD	HD LifeSciences LLC	Primary
K212904/K213359/K241466	WaveForm C Interbody System	SeaSpine Orthopedics Corporation	Additional
K240838	Spectrum Spine Cervical Cage System	Spectrum Spine, Inc.	Additional

There are no differences between the subject and predicate devices which raise questions for the safety and efficacy of the subject devices.

PERFORMANCE DATA

The Hive™ Standalone Cervical System has been tested in the following test modes:

- Static Axial Compression per ASTM F2077
- Dynamic Axial Compression per ASTM F2077
- Static Compression Shear per ASTM F2077
- Dynamic Compression Shear per ASTM F2077
- Static Torsion per ASTM F2077
- Dynamic Torsion per ASTM F2077
- Static Cantilever Bending Testing per ASTM F2193
- Expulsion

The results of this non-clinical testing show that the strength of the Hive™ Standalone Cervical System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

The Hive™ C Interbody System has been previously tested per ASTM F2077 and ASTM F2267 under K180364. This prior testing established substantial equivalence in mechanical performance and was not required for this submission.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Hive™ Standalone Cervical System and Hive™ C Interbody System are substantially equivalent to the predicate device.