December 12, 2022

NanoHive Medical LLC
% Nathan Wright, MS
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K223190
Trade/Device Name: Hive™ Standalone Cervical System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: October 12, 2022
Received: October 13, 2022

Dear Nathan Wright:

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)*
K223190

Device Name
Hive™ Standalone Cervical System

Indications for Use *(Describe)*
The Hive™ Standalone Cervical System with NanoHive® Surface Technology is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 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 or corticocancellous bone. These devices are intended to be used with the screws which accompany the implants. When used with the accompanying screws, these devices may be used as standalone interbody devices. If the accompanying screws are not used, the device is intended for use with supplemental fixation. When used as a standalone system, the Hive™ Standalone Cervical System is intended for use at one or two levels (C2-T1) and must be used with the provided bone screws.

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

Submitter's Name:	NanoHive Medical LLC
Submitter's Address:	12 Gill Street, Suite 4500 Woburn, Massachusetts 01801
Submitter's Telephone:	844-943-5433
Contact Person:	Nathan Wright MS Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	October 12, 2022
Trade or Proprietary Name:	Hive™ Standalone Cervical System
Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical Intervertebral Fusion Device with Bone Graft, Cervical
Classification:	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 and plates made from Ti-6Al-4V per ASTM F136. The titanium cages take the form of a highly porous core which is surrounded at the cephalad and caudal ends by protective solid titanium endplates. The implant is anatomic in shape and has teeth to ensure placement is maintained after implantation. Implants incorporate features for fixating the device to the vertebral body in a stand-alone manner using either interfixated features within the intervertebral space or outer plate fixation on the anterior surface of the vertebral bodies. Inter-fixation and outer-fixation allow adjustable placement of fixation components.

The implant components of the Hive™ Standalone Cervical System are offered in a variety of sizes to accommodate patient anatomy and surgical approach. The implants are also offered in various lordotic configurations to ensure proper stability and alignment of the spine for differing patient anatomy. The implants are provided pre-sterile, in validated sterile packaging, and are single-use only.

INDICATIONS FOR USE

The Hive™ Standalone Cervical System with NanoHive® Surface Technology is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 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 or corticocancellous bone. These devices are intended to be used with the screws which accompany the implants. When used with the accompanying screws, these devices may be used as standalone interbody devices. If the accompanying screws are not used the device is intended for use with supplemental fixation.

When used as a standalone system, the Hive™ Standalone Cervical System is intended for use at one or two levels (C2-T1) and must be used with the provided bone screw.

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
- Principle of Operation
- Structural Support Mechanism
- Materials
- Sterility
- Sizes
- Manufacturing and Biocompatibility

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K212904	SeaSpine WaveForm™ C Interbody System	SeaSpine Orthopedics Corporation	OVE, ODP	Primary
K212853	Cervical Stand-Alone System	Eminent Spine, LLC	OVE	Additional
K190885	Elevation Spine Saber-C System	Elevation Spine	OVE, ODP, KWQ	Additional
K200541	Hive™ Stand-alone Anterior Lumbar Interbody System	HD LifeSciences	OVD, MAX	Reference

PERFORMANCE DATA

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

- Static and Dynamic Axial Compression per ASTM F2077
- Static and Dynamic Compression Shear per ASTM F2077
- Static and Dynamic Torsion per ASTM 2077
- Subsidence per ASTM F2267
- 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.

CONCLUSION

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