April 28, 2023

HAPPE Spine
℅ Meredith P. Vanderbilt
Director of Consulting
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K222004
Trade/Device Name: INTEGRATE™-C Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 29, 2023
Received: March 29, 2023

Dear Ms. Vanderbilt:

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,

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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*

K222004

Device Name

INTEGRATE™-C Interbody Fusion System

Indications for Use *(Describe)*

The INTEGRATE™-C Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The INTEGRATE™-C Interbody Fusion System is intended for use for anterior cervical interbody fusion in 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 - T1. The INTEGRATE™-C Interbody Fusion System is intended to be used with supplemental fixation. The INTEGRATE™-C Interbody Fusion System is designed for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Nonoperative treatment prior to treatment with INTEGRATE™-C Interbody Fusion System is six (6) weeks. INTEGRATE™-C Interbody Fusion Systems are to be implemented via an open anterior approach.

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:	HAPPE Spine, LLC
Submitter's Address:	220 Lyon Street, NW, Suite 500 Grand Rapids, MI 49503
Submitter's Telephone:	+1-616-294-1026
Contact Person:	Meredith Lee May MS, RAC Empirical Testing Corp. 1-719-337-7579 MMay@EmpiricalTech.com
Date Summary was Prepared:	July 6, 2022
Trade or Proprietary Name:	INTEGRATE™-C Interbody Fusion System
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The INTEGRATE™-C Interbody Fusion System implant is made of a single, continuous piece of hydroxyapatite impregnated polyetheretherketone polymer (ASTM F2026 & F1185). The INTEGRATE™-C Interbody Fusion System implant body is monolithic with porous regions derived directly from the implant body, not a sintered or otherwise additive coating, and extended through the device. The device is available in a variety of footprints, lordosis and heights to accommodate variations in the individual pathology and anatomic of the patient. The superior and inferior surfaces of the device contain a pattern of teeth to provide for initial stability. Tantalum (ASTM F560) radiopaque markers are placed in the device to aid in determining the location of the implant intra- and post-operatively.

INDICATIONS FOR USE

The INTEGRATE™-C Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The INTEGRATE™-C Interbody Fusion System is intended for use for anterior cervical interbody fusion in 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 - T1. The INTEGRATE™-C Interbody Fusion System is intended to be used with supplemental fixation. The INTEGRATE™-C Interbody Fusion System is designed for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Nonoperative treatment prior to treatment with INTEGRATE™-C Interbody Fusion System is six (6) weeks. INTEGRATE™-C Interbody Fusion Systems are to be implemented via an open anterior approach.

HAPPE Spine INTEGRATE™-C Interbody Fusion System

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have similar technological characteristics and the differences regarding material composition do not raise any new issues of safety and effectiveness; mechanical and biocompatibility testing have mitigated concerns based on differences in material composition. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Product Code
- Sterility
- Sizes
- Graft Material
- Device Material

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K173030	Cohere®	Vertera Spine™	ODP	Primary
K133784	Vista®-S	Zimmer Trabecular Metal Technology, Inc	ODP	Additional
K172484	A-CIFT™ SoloFuse™	SpineFrontier (LESpine)	ODP, OVE	Additional
K191581	Endoskeleton® TL	Titan Spine	OVD, MAX	Reference

PERFORMANCE DATA

The INTEGRATE™-C Interbody Fusion System has been tested in the following test modes:

- Static and dynamic axial compression per ASTM F2077
- Static and dynamic compressive shear per ASTM F2077
- Static and dynamic torsion per ASTM F2077
- Subsidence per ASTM F2267
- Validation Cadaver Lab
- Static Tension Testing per ASTM F1147
- Dynamic Shear Testing per ASTM F1160
- Static Shear Testing per ASTM F1044

The results of this non-clinical testing show that the strength of the INTEGRATE™-C Interbody Fusion 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 INTEGRATE™-C Interbody Fusion System is substantially equivalent to the predicate device.