April 27, 2018

SpineMED Ges.m.b.H
% John Kapitan
CEO
Kapstone Medical, LLC
PO Box 969
Leicester, North Carolina 28748

Re: K171151
Trade/Device Name: ACRON™ TLIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 21, 2018
Received: March 29, 2018

Dear Mr. Kapitan:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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 below.

510(k) Number *(if known)*
K171151

Device Name
ACRON™ TLIF System

Indications for Use *(Describe)*
The ACRON™ TLIF System is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level 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 I spondylolisthesis at the involved level. The ACRON™ TLIF System is to be used with autogenous bone graft and 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.

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

1. Applicant

SpineMED Ges.m.b.H
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Vienna A-1170
Austria

2. Official Correspondent

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Leicester, NC 28748

Contact Person:
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Fax: (704) 831-5316
Email: jkapitan@kapstonemedical.com

3. Device Name

Trade: ACRON™ TLIF System
Common/Usual Name: Intervertebral Fusion Device, Lumbar
Classification Name: Intervertebral body fusion device
Regulation Number: 888.3080
Product Code: MAX
Classification: II
Panel: Orthopedic

4. Predicate Devices

The SpineMED ACRON™ TLIF System is substantially equivalent to the NuVasive CoRoent System produced by NuVasive, Inc, as shown in Table 1-1.

Predicate	510(k) Number	Device	Manufacturer
Primary	K071795	NuVasive CoRoent System	NuVasive, Inc
Reference	K141665	NuVasive CoRoent System	NuVasive, Inc

Table 1-1: Predicate devices

5. Device Description

The ACRON™ TLIF System is an implant system for a unilateral posterior transforaminal approach (TLIF). It is specially designed for small incision (minimally invasive), resulting in a relatively atraumatic operation for the patient. Implants, used with supplemental fixation and autogenous bone graft, provide improved stability, height restoration and lordosis to optimize fusion. The system is comprised of implantable cages and stainless steel surgical instruments, both general and system specific.

The ACRON™ TLIF System cages are manufactured from radiolucent polymer PEEK-OPTIMA® Optima LT1 (Polyether-ether-ketone) conforming to ASTM standard F2026, to allow for clear assessment of bone fusion. Two radiopaque markers constructed from Tantalum conforming to ASTM standard F560 allow for radiographic visualization of the implant orientation and placement.

The implants have a convex shape and are offered in 4 sizes, in 2mm increments, ranging in height from 7mm to 13mm with lordotic angle of 8°, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. Teeth on the superior and inferior surfaces help the implant to resist expulsion and migration. The geometry includes openings to allow for the packing of autogenous bone graft into the axial canal.

6. Intended Use

The ACRON™ TLIF System is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level 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 I spondylolisthesis at the involved level. The ACRON™ TLIF System is to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

7. Technological Characteristics

As was established in this submission, the subject SpineMED ACRON™ TLIF System are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function and sterilization method.

8. Performance Data

Nonclinical testing was performed to demonstrate that the subject SpineMED ACRON™ TLIF System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic axial compression and compression shear per ASTM F2077
- Subsidence testing and analysis per ASTM F2267

The results demonstrate that the subject SpineMED ACRON™ TLIF System meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicate. No clinical studies were conducted.

9. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the ACRON™ TLIF System has been shown to be substantially equivalent to legally marketed predicate devices.