October 24, 2019

CMF Medicon Surgical Inc.
% David Klementowski
Sr. Consultant
Regulatory Compliance Associates
102 Finwood Dr.
Baldwinsville, New York 13027

Re: K190349
Trade/Device Name: MediExpand TL Expandable VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: September 17, 2019
Received: September 19, 2019

Dear Mr. Klementowski:

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
Ronald P. Jean, Ph.D.
Director (Acting)
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 below.

510(k) Number *(if known)*

K190349

Device Name

MediExpand TL Expandable VBR System

Indications for Use *(Describe)*

The MediExpand TL Expandable VBR System is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore the height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neutral tissues. The MediExpand TL Expandable VBR System is intended to be used with supplemental internal spinal fixations systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Submitter's Name and Address:	CMF MEDICON SURGICAL INC 11200 St. Johns Industrial Pkwy N. Suite 1 Jacksonville, FL 32246 USA
Official Contact:	Matthias Alber
Contact Person and Telephone:	David Klementowski 315-345-9514
Date Summary Prepared:	12/20/2018
Device Name:	*Classification Name* – Spinal Intervertebral Body Fixation Orthosis *Common or Usual Name* - Spinal Vertebral Body Replacement Device *Proprietary Name* – MediExpand TL Expandable VBR System
Device Class:	Class II
Classification:	21 CFR § 888.3060
Product Code:	MQP
Predicate Devices	
Primary Predicate Device:	Nuvasive X-Core Expandable VBR System (K142205)
Additional Predicate Device:	Aesculap HydroLift VBR System (K083186)

510(k) Summary

Device Description:

The *MediExpand TL Expandable VBR System* is an adjustable vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine. The system comprises of vertebral body devices of various heights, sizes and footplates to fit the anatomical needs of a wide variety of patients. The columns can of the device can be adjusted to the exact length required by the patient's anatomy after implantation. Once it is adjusted to the desired length the columns are mechanically locked in place. The devices have a cylindrical space to allow grafting material to be packed inside the devices. Spikes on the footplates improve the anchoring of the implant to the vertebral body. The footplates are available in various lordotic angles. Components are manufactured from titanium alloy (Ti6Al4V) per ASTM F-136 and ISO 5832-3.

Indication for Use:

The *MediExpand TL Expandable VBR System* is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore the height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neutral tissues. The *MediExpand TL Expandable VBR System* is intended to be used with supplemental internal spinal fixations systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

Technological Characteristics:

As was established in this submission, the subject *MediExpand TL Expandable VBR System* is substantially equivalent to the other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent based on having the same technological characteristics to its predicate devices through comparison in areas including design, intended use, performance, material composition, and function.

Performance Testing:

The *MediExpand TL Expandable VBR System* and the predicate devices Nuvasive X-Core Expandable VBR System and Aesculap HydroLift VBR System are similar in design, material, and indicated use, and are both cleared devices.

Static and dynamic testing of the *MediExpand TL Expandable VBR System* was performed in accordance with ASTM F2077 as recommended by the FDA Guidance for Spinal System 510(k)'s.

Conclusion:

Based on the indication for use, technological characteristics, mechanical testing, and comparison to predicate devices, the subject *MediExpand TL Expandable VBR System* has been shown to be substantially equivalent to the legally marketed predicate devices.