April 4, 2022

CMF Medicon Surgical Inc.
Mr. Matthias Alber
Executive Vice President
11200 St. Johns Industrial Pkwy N, Suite 1
Jacksonville, Florida 32246

Re: K212126
Trade/Device Name: MediExpand Cervical Expandable VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: February 28, 2022
Received: March 3, 2022

Dear Mr. Alber:

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 L. 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)*
K212126

Device Name
MediExpand Cervical Expandable VBR System

Indications for Use *(Describe)*
The MediExpand Cervical Expandable VBR System is intended for use in the cervical spine (C3-C7 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. Use of the MediExpand Cervical Expandable VBR System is limited to single-level or two-level corpectomy and the device is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The MediExpand Cervical Expandable VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited period of time in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft 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.

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510(k) Summary

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 Executive Vice President
Contact Person and Telephone:	Matthias Alber 904-642-7500
Date Summary Prepared:	03/31/2022
Device Name:	Classification Name – Spinal Intervertebral Body Fixation Orthosis Common or Usual Name - Spinal Vertebral Body Replacement Device Proprietary Name – MediExpand Cervical Expandable VBR System
Device Class:	Class II
Classification:	21 CFR § 888.3060
Product Code:	PLR

Predicate Devices

Primary Predicate Device:	Nuvasive X-Core Mini Cervical Expandable VBR System (K151651)
Additional Predicate Device:	Aesculap Modulift Vertebral Body Replacement (VBR) System (K172032)

Device Description:

The MediExpand Cervical 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 devices can be adjusted to the required height after implantation. Once it is adjusted to the desired height the device is mechanically locked in place with fixation screws. The devices have a rectangular 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. The devices have threaded holes for anchor screws which can be inserted into the adjacent vertebral bodies. Components are manufactured from titanium alloy (Ti6Al4V) per ASTM F-136 and ISO 5832-3.

Indication for Use:
The MediExpand Cervical Expandable VBR System is intended for use in the cervical spine (C3-C7 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. Use of the MediExpand Cervical Expandable VBR System is limited to single-level or two-level corpectomy and the device is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The MediExpand Cervical Expandable VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited period of time in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

Technological Characteristics:
As was established in this submission, the subject MediExpand Cervical 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 clinical data and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, performance, material composition, and function.

The MediExpand Cervical Expandable VBR System and the predicate devices Nuvasive X-Core Mini Cervical Expandable VBR System and Aesculap Modulift Vertebral Body Replacement (VBR) System are similar in design, material, and indicated use, and are both cleared devices.

Performance Testing:
Static and dynamic testing of the MediExpand Cervical Expandable VBR System was performed in accordance with ASTM F2077.
Clinical data from Europe have shown the clinical performance and support the use of the MediExpand Cervical Expandable VBR System as treatment of tumors, trauma, and degenerative disorders of the cervical spine.

Real World Data (RWD) is presented from three sites in Germany. The clinical data includes results from 338 patients were the MediExpand Cervical Expandable VBR was implanted for vertebral body replacement:
- 40 cases from University Hospital of Ludwig-Maximilians-University (LMU) in Munich
- 258 cases from Central Clinic in Bad Berka
- 40 cases from Schoen Clinic Hamburg Eilbek, Hamburg

This data has been analyzed retrospectively in support of substantial equivalence of the device under 510(k) review. There were no instances of implant failure, and none of the patients suffered from implant associated damages/injuries. The results demonstrate that the subject MediExpand Cervical Expandable VBR System is substantially equivalent to predicate devices.

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