April 14, 2023

Compremium AG
% Philippe Etter
Senior Partner
Medidee Services LLC
300 Welsh Road, Building 1, Suite 100
Horsham, Pennsylvania 19044

Re: K223509
Trade/Device Name: Compremium Compartment Compressibility Monitoring System (CPM#1)
Regulatory Class: Unclassified
Product Code: LXC
Dated: April 3, 2023
Received: April 4, 2023

Dear Philippe Etter:

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K223509

Device Name
Compremium Compartmental Compressibility Monitoring System (CPM#1)

Indications for Use *(Describe)*
The Compartmental Compressibility Monitoring System (CPM#1) is intended for real-time and intermittent monitoring of relative compartment compressibility.

The relative compartment compressibility (CP Value) is not meant for trend analysis.

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	Compremium AG Worbstrasse 46 3074 Muri bei Bern Switzerland
Contact Person	Vincent Baumann, CEO Phone: +41 79 933 96 48 Email: v.baumann@compremium.ch
Date Prepared	April 4th, 2023
Name of Device	Compremium Compartmental Compressibility Monitoring System (CPM#1)
Classification Name	Intracompartmental pressure monitor
Classification Panel	Orthopedic
Classification	Pre-amendment, Unclassified
Product Code(s)	LXC
Predicate Device	MY01 Continuous Compartmental Pressure Monitor (K210525)
Reference Device	Interson USB Ultrasound System (K163443)
Description of Device	The Compartmental Compressibility Monitoring System (CPM#1) is a point-of-care device for non-invasive, real-time, and intermittent monitoring of relative compartment compressibility. The device combines a linear ultrasound array with an integrated pressure sensor into a single handheld probe (CP Probe) to obtain cross-section ultrasound views of the compartment of interest. The device provides a surrogate metric of the compartment's compressibility in one ultrasound image plane only, using a linear measurement of distance between two points of the compartment, as a function of applied external pressure. Based on this measurement, a relative compartment compressibility value is calculated and displayed on-screen as the CP Value.
Indication for Use	The Compartmental Compressibility Monitoring System (CPM#1) is intended for real-time and intermittent monitoring of relative compartment compressibility. The relative compartment compressibility (CP Value) is not meant for trend analysis.

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Comparison of Technological Characteristics with Predicate and Reference Devices	CPM#1 System (Subject Device	MY01 (Predicate Device)	Interson SP-L01 (Reference Device)
510(k) Number	K223509	K210525	K163443
Product Code(s)	LXC	LXC	IYN, IYO, ITX
Indication for Use	The Compartmental Compressibility Monitoring System (CPM#1) is intended for real-time and intermittent monitoring of relative compartment compressibility. The relative compartment compressibility (CP Value) is not meant for trend analysis.	The MY01 Continuous Compartmental Pressure Monitor is intended for real-time and continuous measurement of compartmental pressures. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome. The trend arrows displayed are meant for qualitative purposes only and are not intended to have any clinical significance. The MY01 Mobile Application is an optional application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device. The data is for informational purposes only and is not intended to be used for diagnosis of any nature or active patient monitoring.	The Interson USB Ultrasound System is intended for diagnostic ultrasound imaging in B, color Doppler, or Combined (B + Color) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Pediatric, Small Organ, Musculo-skeletal (conventional), Musculo-skeletal (superficial), Urology, Gynecology, Pelvic Floor, Neuro-muscular, and Peripheral Vessel. The system is intended for use by healthcare professionals.
Design	Non-invasive probe using linear ultrasound array with MEMS pressure sensor, connected to commercial off-the-shelf (COTS) tablet.	Invasive MEMS pressure sensor, LCD display screen, optional mobile application.	Non-invasive probe using linear ultrasound array, connected to commercial off-the-shelf (COTS) tablet.

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Material	ABS housing, medical grade silicone membrane, stainless steel ring. Commercial tablet with USB cable.	Introducer with plastic housing with stainless steel needle, LCD display monitor.	ABS housing. Commercial tablet with USB cable.
Sterilization	No	Yes	No
Single Use	No	Yes	No
Key Differences	The main difference between the subject device and the predicate device is that the method of measurement using the subject device is non-invasive, whereas the predicate device is invasive. In addition, the subject device provides a surrogate metric of the compartment's compressibility in one ultrasound image plane only, while the predicate device provides a direct measurement of compartment pressure. The indications for use differ from the predicate device because the subject device is not indicated for use to aid in the diagnosis of compartment syndrome nor for trend analysis. The subject and predicate device have the same general intended use to measure pressure-related conditions in the extremities.		
Performance Data	The following performance data were provided in support of substantial equivalence. **Biocompatibility Testing** The biocompatibility testing for the CPM#1 System was conducted in accordance with ISO 10993-1:2018, following the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" and with ISO 14971:2019, "Medical devices – application of risk management to medical devices". **Electrical Safety Testing** Electrical safety testing for the CPM#1 System was conducted in accordance with IEC 60601-1:2005/AMD1:2012. EMC testing was also conducted in accordance with IEC 60601-1-2:2014/AMD1:2020. **Usability Testing** Usability testing was conducted in accordance with IEC 62366-1:2015 + A1:2020. **Cleaning and Disinfection Testing** The manual cleaning and low-level disinfection process was validated in accordance with ISO 17664-2:2021. **Ultrasound Performance Testing** The acoustic output of the CPM#1 System was tested in accordance with IEC 60601-2-37:2007/AMD1:2015 and IEC 62359:2.1/AMD1:2017. The image quality was tested to confirm compliance with design input requirements. **CP Value Performance Testing** The accuracy, repeatability, and reproducibility of the CP Value was confirmed using an in-vitro bench test model. The collective results of the nonclinical testing demonstrate that the design, the materials chosen, and the manufacturing processes of the CPM#1 System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the CPM#1 System does not raise different questions of safety or effectiveness for its intended use when compared to the predicate device. **Clinical Testing** A study was performed to validate the repeatability and reproducibility of the CPM#1 System relative compartment compressibility measurements in healthy volunteers.		

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Conclusion	Based on the test results and additional supporting information provided for the CPM#1 System, it is concluded that the subject device is safe and effective for the stated intended use and is substantially equivalent to the predicate device.