Cerebrotech Medical Systems
% Pamela Buckman
Consultant
Pamela M. Buckman, Msn
2800 Pleasant Hill Rd. #175
Pleasant Hill, California 94523

December 8, 2017

Re: K171186
Trade/Device Name: Cerebrotech CMS-5000
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: QAF
Dated: November 7, 2017
Received: November 8, 2017

Dear Ms. Buckman:

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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K171186

Device Name
Cerebrotech CMS-5000

Indications for Use *(Describe)*
The CMS-5000 is a bioimpedance spectroscopy device for use on adult human patients utilizing impedance ratios that are displayed as a B-DEX ratio as an aid in the assessment of fluid volume differences between the cerebral hemispheres in patients undergoing neurologic assessment.

The CMS-5000 is an adjunct to standard methodologies routinely used in the clinical evaluation of intracranial fluid distribution and is not intended to be a sole determinant.

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

K171186

1. General Information

Submission Sponsor:

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Submission Contact:

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Date Prepared: December 8, 2017

2. Device Identification

Device Name:	Cerebrotech™ CMS-5000™
Classification Name	Impedance Plethysmograph
Classification Regulation:	21 CFR Part 870.2770
Classification Panel:	Neurology
Product Code:	QAF
Device Class:	Class II

3. Predicate Device

K130338, Impedimed L-Dex U400, Impedance Plethysmograph

4. Device Description

The CMS-5000 is a bioimpedance spectroscopy device used to monitor patients who have conditions that predispose them to fluid volume changes. The device uses Volumetric Integral Phase-Shift Spectroscopy (VIPS) technology. Changes in the volume of fluids in the human skull can be detected by monitoring changes in electrical properties. VIPS technology measures the frequency response of the phase angle shift between an emitter antenna and a detector antenna, when placed on opposite sides of the head. The device is intended to be used as an aid to clinical assessment in conjunction with current standards of care.

5. Indications for Use

The CMS-5000 is a bioimpedance spectroscopy device for use on adult human patients utilizing impedance ratios that are displayed as a B-DEX ratio as an aid in the assessment of fluid volume differences between the cerebral hemispheres in patients undergoing neurologic assessment. The CMS-5000 is an adjunct to standard methodologies routinely used in the clinical evaluation of intracranial fluid distribution and is not intended to be a sole determinant.

6. Comparison of Technological Characteristics

The technological characteristics of the CMS-5000 are substantially equivalent to those of the predicate device.

Technological Characteristics Comparison Table		
Characteristic	Impedimed L-Dex U400	Cerebrotech Fluids Monitor CMS-5000
Monitoring Mode	Periodic. Baseline, then repeated as required	Periodic. Baseline, then repeated as required
Operating Principle	Multi-frequency Bioimpedance Spectroscopy	Multi-frequency Bioimpedance Spectroscopy
Embedded Software	Yes	Yes
Type of Energy	Electric Current	Low-Power Radio Frequency
Frequency Range	30-310 MHz	4-1000 KHz
Displayed parameter	Bioimpedance ratio	Bioimpedance ratio
Device Configuration	Non-invasive, antenna modules and system controller	Non-invasive; adhesive contact electrode modules, system controller
Power Source	Rechargeable Battery	Rechargeable Battery
Performance	Device detects and monitors bioimpedance ratios	Device detects and monitors bioimpedance ratios
Voltage	100-240	100-240
Frequency	50-60 Hz	50-60 Hz
Current	1A Apple MagSafe 2 Power Adapter (for recharging Console) 0.2A Cell-Con plug (Scanner Battery Recharger)	Not available

7. Substantial Equivalence

The compared systems utilize the same multi-frequency bioimpedance spectroscopy technology to measure tissue fluid differences between contralateral anatomies. Bioimpedance has been used for decades to measure tissue fluids in many anatomical regions, including limbs, lungs, brain, and large portions of the body for body composition analysis. While the type of energy used for monitoring differs between the CMS-5000 (Low-Power RF) and L-Dex U400 (Current), the principles of comparison are similar. The differences between the CMS-5000 and the L-Dex U400 identified above introduce no additional risks.

8. Safety and Effectiveness information

The CMS-5000 and the L-Dex U400 use the same technical principles to achieve the same goal: to provide information about tissue fluid differences derived from bioimpedance ratios. Both are intended to supply adjunct information and do not replace standard diagnostic techniques, which may include physical examination, medical imaging, and professional judgment. The systems are therefore substantially equivalent.

9. Non-Clinical Performance

The performance of the CMS-5000 was validated in a series of bench tests, including the use of standardized, validated bioimpedance human head phantoms. In addition, all required standardized testing was completed, including IEC 60601 tests. The results of all performance, verification and validation testing showed no new issues of safety or efficacy.

Summary of Performance Data

The bioimpedance index, or B-DEX, is a proprietary index derived from the electrical signals received by the CMS-5000 across the range of device frequencies. B-DEX asymmetry is the percent difference in B-DEX between the two hemispheres (right minus left, divided by the average). A series of studies were conducted to establish device performance.

Study	Description
Normative human bioimpedance measurements	79 healthy adult volunteers established normative human bioimpedance and person-to-person variability.
Detection of bioimpedance asymmetry	Human head phantom with a septum dividing the right and left halves was used to measure bioimpedance asymmetry between the two hemispheres.
Mathematical model	A mathematical model validated the accuracy of the bioimpedance asymmetry readings.
Measurement of bioimpedance asymmetry during head tilt	Demonstrated the ability to detect a bioimpedance asymmetry induced by gravity.
Measurement Stability (human)	Demonstrated day-to-day measurement stability in human subjects.
Measurement Stability (human head phantom)	Demonstrated day-to-day measurement stability of the device, independent of human day-to-day variability.

10. Clinical Performance

There was no clinical testing required to support this medical device as the indications for use and technology are equivalent to those of the predicate devices.

11. Statement of Substantial Equivalence

A device is substantially equivalent when the subject device has the same intended use and the same technological characteristics as the previously cleared predicate device(s). The CMS-5000 component change from patient contacting electrodes in the predicate device to a non-contact antenna technology does not alter either of these characteristics and does not raise any new questions of safety or efficacy as compared to the predicate.

12. Conclusion

The Cerebrotech CMS-5000 was found to be substantially equivalent to the predicate device. It shares the same indications for use, similar design features as well as functional features and thus is substantially equivalent to the predicate device.