DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 12, 2015

Mespere Lifesciences Inc.
Helen Tan
Vice President
180 Frobisher Dr, Unit 1C
Waterloo, Ontario, N2V2A2 CA

Re: K151776
Trade/Device Name: Central Venous Pressure System – Mespere Venus 2000
Regulation Number: 21 CFR 870.1140
Regulation Name: Venous Blood Pressure Manometer
Regulatory Class: Class II
Product Code: PFA
Dated: July 9, 2015
Received: July 15, 2015

Dear Helen Tan:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 006 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known):

Device Name: Central Venous Pressure System - Mespere Venus 2000

Indications for Use: CVP-VENUS-2000 is intended to be used by healthcare professionals for assessment of central venous blood pressure (CVP) of adult individuals.

Prescription Use _Yes____ AND/OR Over-The-Counter Use ___No____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 007

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510(k) SUMMARY

Submitted by:	Mespere LifeSciences Inc. 180 Frobisher Drive, Unit 1C Waterloo, Ontario, Canada N2V 2A2 Phone : 1(519) 884-7575 Fax: 1(519) 884-8810
Company contact:	Helen Tan, Vice President
Date summary prepared:	11/05/2015
Trade name:	Central Venous Pressure System – Mespere Venus 2000
Common name:	CVP System
Classification name:	870.1140 (Product code PFA)
Classification:	Class II Medical Device
Predicate Device:	K131085 Central Venous Pressure System – Mespere Venus 1000 Product code: PFA Regulation number: 870.1140

Device Description:

The Mespere LifeSciences Inc. CVP-VENUS-2000 Central Venous Pressure System is used to indicate right heart pressure at the superior vena cava, which is clinically referred to as central venous pressure (CVP).

The Venus 2000 is a modified version of Venus 1000 which has been cleared by FDA. The modification is to improve the detection sensitivity, data managements, and usability. The main improvements are moving the analog to digital conversion chip from the handheld to the sensor head to reduce cable noise and enhance the sensitivity; using a tablet/laptop instead of the handheld unit for faster speed of signal

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processing and easier data management; and using lighter sensor cable and smaller sensor head to enhance usability.

The Venus 2000 system has the same fundamental scientific technology and intended use as the predicate device, the Venus 1000 System.

The device is intended for use in hospital and clinical environments by healthcare professionals.

Intended Use/Indications For Use:

The Venus 2000 System is intended to be used by healthcare professionals for assessment of central venous blood pressure (CVP) of adult individuals.

Technology Characteristics:

The Venus 2000 System and the predicate device, the Venus 1000 System, have the same intended use and technology characteristics. The Venus 2000 System and the Venus 1000 System are both based on non-invasive near infrared spectroscopy (NIRS) technology. The core hardware and software design of the Venus 2000 was kept the same as the Venus 1000, including key components such as light emitters, photo detectors, signal processing, and algorithm.

Complied Standards:

The design of the Mespere Venus 2000 device conforms to the following voluntary standards:

- IEC 60601-1: 2005 + A1 2012 – edition 3.0
- IEC 60601-1-2: 2007 - edition 3.0
- IEC 60601-1-6: 2010
- IEC/ISO 62366:2007
- ISO 14971:2007
- ISO 14155:2011
- IEC/EN 62304:2006
- EN 1041:2008
- ISO 15223-1:2012
- ISO 13485:2003

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- ISO 10993-1:2009
- ISO 2859-1:1999

Tests:

The Venus 2000 System was subjected to extensive safety testing, performance testing, verification, and validation testing.

The third party tests against IEC 60601-1: 2005 + A1 2012 and IEC 60601-1-2: 2007 of the Venus 2000 System ensured that the device met the industry and safety standards.

The system test of the Venus 2000 System ensured that the device met all its functional specifications.

The bench top test verified that the Venus 2000 System has the same performance as Venus 1000 System and the Venus 2000 System met the design requirements in an ideal non-clinical environment.

There are no further clinical tests required for the Venus 2000. The clinical performance of the Venus 1000 System has been verified and validated. The Venus 2000 system was a device modification. It continues to meet the requirements to patient safety and effectiveness.

Substantial Equivalence of Performance:

The Venus 2000 device is substantially equivalent to the predicate device, the Venus 1000 System, in terms of the performance and the technology safety and effectiveness.

Conclusions:

The conclusions drawn from the above testing is that the CVP-VENUS-2000 Central Venous Pressure System is substantially equivalent to the predicate device, the CVP-VENUS-1000 Central Venous Pressure System.