August 17, 2018

Hitachi Healthcare Americas
Doug Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
Twinsburg, Ohio 44087

Re: K172492
Trade/Device Name: Optical Topography System ETG-4100
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 13, 2018
Received: July 17, 2018

Dear Doug Thistlethwaite:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Matthew C. Krueger -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)*
K172492

Device Name
Optical Topography System ETG-4100

Indications for Use *(Describe)*
The intended use of the ETG-4100 is the measurement of relative levels of cerebral deoxyhemoglobin and oxyhemoglobin.

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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K172492 510(k) Summary

Submitter Information

Submitter:	Hitachi Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
Contact:	Douglas J. Thistlethwaite
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Date:	August 17, 2018

Subject Device

Trade/Proprietary Name:	Optical Topography System ETG-4100
Regulation Number:	21 CFR 870.2700
Regulation Name:	Oximeter
Product Code	DQA
Class	II
510(k) Review Panel	Neurology

Predicate Device

Trade/Proprietary Name:	**K042501** Optical Topography System ETG-4000
Regulation Number:	21 CFR 870.2700
Regulation Name:	Oximeter
Product Code	DQA
Class	II
510(k) Review Panel	Anesthesiology

Device Intended Use

The intended use of the ETG-4100 is the measurement of relative levels of cerebral deoxyhemoglobin and oxyhemoglobin based on the amount of reflected or scattered radiation following transmission of radiation at known wavelengths through blood.

Indications for Use

The intended use of the ETG-4100 is the measurement of relative levels of cerebral deoxyhemoglobin and oxyhemoglobin. (Rx Use)

Device Description

The Optical Topography System ETG-4100 is a device that measures and displays relative changes of oxy-hemoglobin, deoxy-hemoglobin and total hemoglobin in the cerebral cortex at multiple points on the head. The ETG-4100 system emits near-infrared light (670-1300nm) of two different wavelengths (695nm and 830nm) that can efficiently penetrate the skull where the light is scattered, absorbed by hemoglobin and unabsorbed light is reflected back.

Physical and Performance Characteristics

Light-emitting and detecting optical fibers are arranged in fiber holders in specific configurations which can be attached in numerous positions to the subject's head via flexible head caps. The ETG-4100 system detects the reflected light and calculates the relative changes of oxy-hemoglobin, deoxy-hemoglobin and total hemoglobin based on the difference between injected and reflected light.

The technology is non-invasive and less restraining for the subject, reducing discomfort considerably in comparison to other brain imaging technologies. The spring-loaded fiber tips provide efficient contact between fiber tip and scalp. Contact between fiber tip and scalp is indicated by a shaft that protrudes from the top of the fiber tip when the fiber tip touches the scalp; the firmer the contact, the more the shaft protrudes.

The ETG-4100 is equipped with a highly sensitive avalanche photodiode allowing the use of

relatively low light intensities, reducing potential harm to the subject and extending the lifetime of the laser diodes.

Simultaneous measurement of all measurement channels is achieved by frequency-modulating the light intensity of each individual light source. The frequency of reflected near infrared light is analyzed by a lock-in amplifier which assigns the incoming signals to their respective measurement channel based on their frequencies.

The individual frequencies of the emitted near infrared light are different from that of daylight or artificial indoor light, the ETG-4100 can be operated under daylight conditions. Measured changes in hemoglobin concentrations can be displayed as time-course graphs or as 2D or 3D topographic images.

Comparison of Technological Characteristics

The technological characteristics of the Optical Topography System ETG-4100 as compared to the predicate are listed in the following table.

Where applicable, differences are discussed in detail in the comment table that follows the comparison table below to demonstrate how these characteristics compare to the predicate.

ITEM	K172492 OPTICAL TOPOGARAPHY SYSTEM ETG-4100	K042501 OPTICAL TOPOGRAPHY SYSTEM ETG-4000	DIFFERENCE
System Configuration			
Illustration			See 01
Indications for Use	The intended use of the ETG-4100 is the measurement of relative levels of cerebral deoxyhemoglobin and oxyhemoglobin. (Rx Use)	The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxyhemoglobin and oxyhemoglobin. (Rx use)	No
Dimensions	582(W)×933(D)×1,430(H)mm	560(W)×933(D)×1,470(H)mm	See 01
Weight	165kg	130kg	See 01
Power Source	AC100/120V 500VA AC220/230/240V 700VA	AC100/120V 500VA AC220/230/240V 700VA	No
Holder and Probe Configurations			
3x3 holder	Yes	Yes	No
4x4 holder	Yes	Yes	No
3x5 holder	Yes	Yes	No
3x11 holder	Yes	Yes	No
2x11 holder	Yes	No	See 02
4x4DD holder	Yes	No	See 02
3x5DD holder	Yes	No	See 02
3x5MD holder	Yes	No	See 02
3x5 Neonate/ Infant probe	Yes	Yes	No
3x3 Neonate/ Infant probe	Yes	Yes	No
Non-magnetic Probe Type T	Yes	No	See 03
Non-magnetic probe type M (length: 7.5m)	Yes	No	See 03
Non-magnetic probe type M (length: 10.5m)	Yes	No	See 03
Fiber Configurations			
Removable Infant Fiber	Yes	No	See 04
Long Fiber(length:5.5m)	Yes	No	See 05
Long Fiber(length:6.5m)	Yes	No	See 05
Measurement Parameters			
Oxyhemoglobin concentration	Yes	Yes	No
Deoxyhemoglobin concentration	Yes	Yes	No

ITEM	K172492 OPTICAL TOPOGARAPHY SYSTEM ETG-4100	K042501 OPTICAL TOPOGRAPHY SYSTEM ETG-4000	DIFFERENCE
Total hemoglobin concentration	Yes	Yes	No
Light Source Configurations			
Light component	Laser diode	Laser diode	No
Wavelength	695, 830nm	695, 830nm	No
Output	4mW/wavelength	4mW/wavelength	No
Device Model	L9135-41 (695nm), Hamamatsu HL8837MG-A (830nm), Ushio Opt	L9135-41 (695nm), Hamamatsu HL8837MG-A (830nm), Ushio Opt	No
Detection method	Frequency modulated locked-in amplifier (Frequency range: 12.0 to 23.8kHz)	Frequency modulated locked-in amplifier (Frequency range: 12.0 to 23.8kHz)	No
Sampling rate	10Hz	10Hz	No
Emitters	18	18	No
Laser safety	IEC 60825-1, Class 1M	IEC 60825-1, Class 1M	No
Source detector separation distance	30 mm for adult and child 20 mm for neonate, infant and child	30 mm for adult and child 20 mm for neonate, infant and child	No
Detector			
Detector component	APD	APD	No
Detectors	16	16	No
Model	C8546, Hamamatsu	C8546, Hamamatsu	No
Maximum No. of Channels	52	52	No
Computer			
Operating system	Windows7 (64bit)	Windows2000 (32bit)	See 06
Features			
Interface for the video recording system	Yes	Yes	No
3D Positioning Unit	Yes	Yes	No
3D Composite Display Unit	Yes	Yes	No
Task Presentation System VFT	Yes	No	See 07
Task Presentation System Custom	Yes	No	See 07
Report Display System VFT	Yes	No	See 08
Report Display System Custom	Yes	No	See 08
Double Density Function	Yes	No	See 09
Multi-Distance ICA Function	Yes	No	See 010
PCA Analysis	Yes	No	See 011
Multi Data Analysis	Yes	No	See 011
Waveform Analysis	Yes	No	See 011
Real-time Output	Yes	No	See 012

Discussion of differences between the predicate device and the Optical Topography System ETG-4100 are explained in the table below.

System Configuration	
01	The differences in appearance, weight, and size have no effect on the safety and effectiveness of the device.
Holder and Probe Configurations	
02	The differences in size and/or optical fiber layout have not effect on the safety, effectiveness and performance of the device.
03	Changing the holder material to non-magnetic material while retaining the other specifications of the predicate holders does not effect on the safety, effectiveness and performance of the device.
Fiber Configurations	
04	This fiber is for Infant use with shape of tip smaller than previous fiber for adult. However, the other specifications are same as previous neonate/infant probe. Therefore, they have no effect on the safety, effectiveness and performance of the device.
05	These fibers are longer than previous fiber (normally 3.5m) . The longer fibers have a smaller transparent which reduces the power to the patient. Therefore safety is improved with no effect on effectiveness.
Computer	
06	Changing from Windows2000 (32bit) to Windows7 (64bit) has no effect on the safety and effectiveness of the device.
Features	
07	These features present tasks to the patient during the measurement. Therefore, they have no effect on the safety, effectiveness and performance of the device.
08	These features display the measurement results in the above task presentation system. Therefore, they have no effect on the safety, effectiveness and performance of the device.
09	The Double Density option overlays a standard 3x5 or 4x4 fiber configuration with a second set of detectors and emitters resulting in a spatial resolution twice that of the standard configuration. Therefore, they have no effect on the safety and effectiveness and minimal effect on performance of the device.
010	Multi-Distance Measurement Function performs two different SD distance measurements and separates hemoglobin data into deep components and shallow blood flow components. Therefore, they have no effect on the safety and effectiveness and minimal effect on performance of the device.
011	These features provide additional data analysis techniques which no not affect the measurement function. Therefore, they have no effect on the safety, effectiveness and performance of the device.
012	This feature allows hemoglobin data to be sent in real time to the PC through the LAN during measurement. Therefore, they have no effect on the safety, effectiveness and performance of the device.

Therefore, based on a thorough analysis and comparison of the Optical Topography System ETG-4100 and the predicate device, the technological characteristics do not impact safety and effectiveness.

Substantial Equivalence

Substantial Equivalence was based on analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance testing which are summarized in the following table:

ITEM	OVERALL RATIONALE ANALYSIS
System Configuration	Based on that there are no significant differences from the predicate device, Hitachi judges that the Optical Topography System ETG-4100 has no additional issues with safety and effectiveness.
Holder and Probe Configurations	
Fiber Configurations	
Measurement Parameters	
Light Source Configurations	
Detector	
Computer	
Features	Based on results of design inspection as confirmed in the Declaration of Conformity, Hitachi judges that the Optical Topography System ETG-4100 device has no additional issues with safety and effectiveness.

Summary of Non-Clinical Testing

The Optical Topography System ETG-4100 is in conformance with the applicable parts of the following standards:

1. Signal stability testing for the subject device and predicate device were submitted to show that the new characteristics produce matching results and output.
2. Software verification and validation reports were submitted to account for the new features proposed in the subject device. These reports demonstrate that the subject device with these new features is substantially equivalent to the predicate since the methods acceptably demonstrate that the algorithm that achieves the intended use (measurement of the relative levels of cerebral deoxyhemoglobin and oxyhemoglobin) as compared to the predicate.
3. AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012

   Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
4. IEC 60601-1-2 Edition 3: 2007

   Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5. IEC 60825-1 Edition 2.0 2007-03

   Safety of laser products - part 1: equipment classification, and requirements
6. IEC 62304:2006

   Medical Device Software - Software Life Cycle Processes.
7. IEC 60601-1-6 Edition 3.1 2013-10

   Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
8. ISO 10993-1 Fourth edition 2009-10-15

   Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process [including: technical corrigendum
9. ISO 10993-5 Third edition 2009-06-01

   Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity. (Biocompatibility)

10. ISO 10993-10 Third Edition 2010-08-01

    Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization. (Biocompatibility)

Conclusions

The proposed Optical Topography System ETG-4100 is considered substantially equivalent to the currently marketed predicate device (Optical Topography System ETG-4000 (K042501) in terms of design features, fundamental scientific technology, intended use, and safety and effectiveness.

Based on the technological characteristics and performance testing to account for any differences in those characteristics, Optical Topography System ETG-4100 is substantially equivalent to the Optical Topography System ETG-4000 (K042501).