September 23, 2019

Spectros Corporation
Bill Curnan
Manager QA/RA
274 E Hamilton Ave Suite H
Campbell, CA 95008

Re: K192322
Trade/Device Name: T-Stat 2.0 Microvascular Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: August 23, 2019
Received: August 27, 2019

Dear Bill Curnan:

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,

Purva Pandya
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192322

Device Name
T-Stat™ 2.0 Microvascular Tissue Oxometer

Indications for Use *(Describe)*

The Spectros T-Stat™ 2.0 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO2%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

The prospective clinical value of measurements made with the T-Stat™ Oximeter has not been demonstrated in disease states. The T-Stat™ Oximeter should not be used as the sole basis for diagnosis or therapy.

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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K192322

510(k) Summary

I. Applicant Information

A. Applicant:

Spectros Medical Devices Inc.
274 E Hamilton Ave #H
Campbell, CA 95008

B. Official Contact:

Bill Curnan
Manager of Quality/Regulatory
Spectros Medical Devices Inc.
274 E Hamilton Ave #H
Campbell, CA 95008
bcurnan@spectros.com

C. Date of Summary: 9/21/19

II. Device Information

A. Proprietary Name : T-Stat™ 2.0 Microvascular Tissue Oximeter

B. Common Names: Tissue Oximeter, Somatic/Cranial Oximeter

C. Classification Name: Oximeter, Tissue (870.2700)

D. Product Code: MUD

E. Regulatory Class: II

F. Panel: Cardiovascular

III. Predicate Device

The device in this 510(k) represents a modification to the T-Stat 303™ Microvascular Tissue Oximeter approved in 510(k) K081233 which is the predicate device.

IV. General Description

The Spectros T-Stat™ 2.0 Microvascular Tissue Oximeter is a broadband, multiwavelength, Visible Light Spectroscopy (VLS) monitoring system for measuring the saturation of hemoglobin with oxygen in the microvascular tissue spaces (StO2%).

The complete system consists of a disposable sensor probe connected to a software-driven electronic monitor. Data collection, analysis, and display functions are provided by the monitor. Illumination of the tissue is provided by a visible light source in the sensor probe placed near, on, or into the target tissue to be studied. Reflected light is captured and returned to the monitor via a detachable connection at the monitor end of the patient probe. StO2% is estimated using differential optical diffuse reflectance spectroscopy and fitting for background scattering over a range of reflected visible wavelengths**.**

V. Indications

The Spectros T-Stat™ 2.0 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO2%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

The prospective clinical value of measurements made with the T-Stat™ Oximeter has not been demonstrated in disease states. The T-Stat™ Oximeter should not be used as the sole basis for diagnosis or therapy.

VI. Comparison to Predicate

The system in this 510(k) represents a modification to the T-Stat303™ Oximeter System described in the predicate 510(k), K081233. These modifications consist of

1. Monitor housing changed from molded plastic to all metal.
2. Obsolete display, motherboard, and power supply replaced.
3. Internal circuit boards consolidated.
4. Addition of battery backup and Wi-Fi data download features.
5. Updated software to work on windows 10 Pro and added modules for indication of battery status and Wi-Fi data download capability.

VII. Test Summary

Validation testing was determined based upon an ISO14971 risk analysis.

A. Monitor tests on the re designed monitor consist of re-verification of compliance with IEC60601-1-2 and IEC 60601-1.
B. Software updates were implemented in compliance with IEC 62304 and validated using an in house validation procedure as well as automated testing and code reviews.
C. Functional continuity was confirmed through reverification of the predicate device hardware and software functional requirements using the predicate device protocols.

VIII. Conclusions

Based upon the above test results the modified T-Stat 303™ Oximeter System represents an improvement over the predicate providing additional features, equivalent safety performance.