DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 15, 2016

Falck Medical, Inc.
Francis Y. Falck, Jr., M.D., Ph.D., M.S.
Chair, Scientific Advisory Board
35 Washington Street
Mystic, CT 06355

Re: K151491
Trade/Device Name: Falck Medical Multifunction Tonometer, FAT1
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY, HPK, NJJ
Dated: December 7, 2015
Received: December 14, 2015

Dear Dr. Falck:

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,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151491

Device Name
Falck Medical Multifunction Tonometer, FAT1

Indications for Use *(Describe)*
The Falck Medical Multi-function Tonometer (FAT1) is indicated for the measurement of intraocular pressure, ocular pulsatile amplitude, force (Ophthalmodynamometry) and estimating conventional outflow facility with calibrated force application (Indentation Tonography).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Information:

1. Company Name/Address: Falck Medical, Inc.
35 Washington Street
Mystic, CT 06355
860-536-9000

2. Contact Information: Francis Y. Falck, Jr., M.D., Ph.D., M.S.
CEO, Chair Scientific Advisory Board

3. Manufacturing Location: VR Industries, 333 Strawberry Field Road,
Warwick, RI 02886

Device Information:

1. Device Trade Name: Falck Medical Multi-Function Tonometer (FAT1)

2. Classification Name: Tonometer

3. Classification Panel: 86 (Ophthalmic)

4. Classification Number: 886.1930

5. Product Codes: HKY, HPK, NJJ

Substantial Equivalence:

The Falck Medical Multi-Function Tonometer, (FATl) is substantially equivalent to the FAT2 device (K071755) for the measurement of intraocular pressure, ocular pulsatile amplitude and the force required to observe pulsation of the central retinal artery (Ophthalmodynamometry). The FAT1 device is technically and functionally equivalent to the Falck Medical, Inc. FAT2 device. The FAT1 device is also substantially equivalent to the Model 30 Classic Pneumatonometer with Tonography Option (K002395) for measuring the change in intraocular pressure with force application from the outflow of aqueous humor through the conventional outflow system (indentation Tonography).

Intended Use:

The Falck Medical Multi-function Tonometer (FAT1) is indicated for the measurement of intraocular pressure, ocular pulsatile amplitude, force (Ophthalmodynamometry) and estimating conventional outflow facility with calibrated force application (Indentation Tonography).

Device Description:

The Falck Medical Multi-function Tonometer (FAT1) mounts on the slit lamp microscope. The device has a floating prism arm which holds a disposable plastic prism. The device has a detection system located in the prism arm head that prevents re-use of the prism.

The prism optical system uses the principle of total internal reflectance. Sampling is every 7 milliseconds and multiple samples are obtained for each measurement. Each measurement is statistically analyzed for repeatability and accuracy. Intraocular pressure is measured using the Imbert-Fick method of applanation. Force application is controlled by the microprocessor. The ocular pulsatile amplitude and central retinal artery pulsation with force application is optically captured. Indentation tonography methodology using calibrated force application is used to measure conventional outflow facility.

Performance Testing:

The disposable prism was tested for biocompatibility. The prism and prism material in cyto-toxicity, systemic toxicity and ocular irritation testing was found to be non-toxic and safe. The FAT1 device is technically and functionally equivalent to the FAT2 device for the measurement of intraocular pressure, ocular pulsatile amplitude and the force required to observe pulsation of the central retinal artery. The accuracy and safety of the FAT2 device for the measurement of intraocular pressure, ocular pulsatile amplitude and the amount of force required to observe pulsation of the central retinal artery was demonstrated in performance testing in 510(k) K071755 and in additional correspondence with the Food and Drug Administration, Office of Device Evaluation dated 11/03/2009 and 01/10/2010 -FMI.

Bench testing and clinical testing done under FDA guidance with IDE (1080757) for the measurement of conventional outflow facility demonstrated the safety, repeatability, precision and accuracy of the FAT1.