K071755

510(k) SUMMARY

JUN - 3 2008

1. Submitter Information:
   A. Company Name/Address: Falck Medical, Inc.
   35 Washington Street, Suite 2
   Mystic, CT 06355
   (860) 536-9000
   (860) 536-9000 FAX

   B. Contact Person: Francis Falck, Jr., M.D., PhD, M.S.
   CEO and President

   C. Manufacturing Location: To be determined

2. Device Information:
   A. Device Trade Name: Falck Medical Applanation Tonometer (FAT 2)
   B. Classification Name: tonometer
   C. Classification Panel: 86: ophthalmic
   D: Device Classification Number: 886.1930
   E. Product Codes: HKY, HKX

3. Substantial Equivalence:

The Falck Applanation Tonometer Model 2 (FAT 2) is substantially equivalent to the Goldmann Applanation Tonometer SL 900, (K981432). The device is based on the Imbert – Fick Law and uses applanation of the cornea to measure the intraocular pressure.

Additionally, the FAT 2 is substantially equivalent to the Langham Model 201 Tonograph/Tonometer (K010998) for the measurement of ocular pulsatile amplitude.

The list of equivalent devices follows:

K981432	1/12/1999	Goldmann Tonometer	Golden Vision, Inc.
K010998	6/27/2001	Model 201 Tonograph/Tonometer	Langham Ophthalmic Technologies

4. Intended use:

The Falck Medical Applanation Tonometer (FAT 2) is indicated in the measurement of intraocular pressure and ocular pulsatile amplitude.

5. Device Description:

The Falck Medical Applanation Tonometer (FAT 2) measures the intraocular pressure by applanation of the cornea uses a disposable sterile plastic prism. It is used as an accessory to a slit lamp microscope. Internal software is used for error checking and calibration. The disposable prism is mounted on a free floating counterweighted arm. When the prism comes into contact with the cornea, the initial applanation area is determined by the biomechanics of the cornea. Force is then actively applied to the cornea and measurements are taken every 13.8 milliseconds. Multiple readings are taken and statistical analysis is performed to ensure repeatability. The measurement principle is the same as the Goldmann, but adjustments are made for variations in surface wetness and corneal resistance. The size of the applanation

area is objectively determined by using visible light and the principle of total internal reflectance (TIR).

A new sterile disposable prism is required prior to each new patient. In addition to intraocular pressure, the device also measures ocular pulsatile amplitude by recording the change in the applanation signal that occurs with the cardiac cycle. The measurement of ocular pulsatile amplitude is similar to the Langham methodology.

6. Performance Testing

Biocompatibility and Toxicity Testing

The disposable prism is designed to come into contact with the cornea for a short period of time. Biocompatibility testing was performed on the prism and prism material to establish a safety profile for the device. Toxicity testing included cytotoxicity, ocular irritation, and systemic toxicity. All testing was found to be non-toxic to ocular and systemic tissues.

Manometric Study Summary

In a comparative study of Falck Applanation Tonometer readings to a reference u-tube mercury manometer using human eye bank eyes, the following results were obtained:

- Average Coefficient of Variation: 2.6% +/- 0.10 (5 to 50mmHg).
- Average Standard Deviation: 0.7 mmHg +/- 0.4, range 0.09 – 1.26, (5 to 50mmHg).

Clinical Trial Summary

In a clinical trial comparing the Falck Applanation Tonometer to a reference Goldmann applanation tonometer for IOP measurement in 205 eyes, the following results were obtained:

- Average Mean Difference between Falck Applanation Tonometer and the Goldmann Applanation Tonometer: 0.7mmHg, SD=2.0, r^2= 0.93, (9 to 56mmHg).

7. Device Comparisons (Similarities and Differences) to Predicate Devices

Function	Falck (FAT 2) Subject of 510(k)	Goldmann SL 900 Tonometer K981432	Langham Ocular Blood Flow (OBF) Tonograph-Tonometer K010998
Measurement independent of corneal resistance	Yes	No	No
Topical anesthetic use	Yes	Yes	Yes
Fluorescein use required	No	Yes	No
Measures ocular pulse	Yes	No	Yes
Ocular Pulsatile Amplitude	Yes	No	Yes
Patient position during test	Sitting only	Sitting only	Sitting / Supine
Force application of tonometer arm	Automatic	Manual	Pneumatic
Skill level required	Trained Assistant	Trained Assistant	Trained Assistant
Requires slit lamp	Yes	Yes	No
Sampling Frequency	145 samples per second	60 seconds	100 samples per second
Electronic	Yes	No	Yes
Data capture	Yes	No	Yes
Data communication	Yes	No	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2008

Falck Medical, Inc
c/o Richard E. Lippman O.D., F.A.A.O.
VP Ophthalmic Product Regulatory Affairs
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Rd., Suite 30
Rockville, MD 20850

Re: K071755
Trade Name: Falck Applanation Tonometer (FAT 2)
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKY, HPK, NJJ
Dated: May 19, 2008
Received: May 19, 2008

Dear Dr. Lippman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

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

Indications for Use

510(k) Number (if known): K071755

Device Name: Falck Medical Applanation Tonometer Model 2 (FAT 2)

Indications for Use:

The Falck Medical Applanation Tonometer Model 2 (FAT 2) is indicated in the measurement of intraocular pressure and ocular pulsatile amplitude.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(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)

5/30/2008

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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