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K991840

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SUMMARY

Trade Name: FPT/Fresco Phosphene Tonometer

Common Name: Pressure Phosphene Tonometer/Eyelid Tonometer

Classification Name: Tonometer for clinical and home self-testing, as per 21CFR § 886.1930

Description

The phosphene tonometer is a pressure measuring device which consists of three ABS plastic components which are moulded, and a stainless 312 metal spring. These fit together and comprise the body of the instrument, a probe with the spring within and a fiduciary, with reset potential.

Intended Use

Tonometer for measuring intraocular pressure in clinical and home test use. Allows for self-testing, as it is applied to the eyelid, and has a subjective end point.

Technological Characteristics

The pressure phosphene tonometer differs from the Goldmann tonometer in that it is utilised on a closed eyelid instead of the cornea, and it requires a subjective response [perception of a phosphene]. It has no power source requirements.

Study Results

1. Clinically 90% of measurements with the device were within + and –3 mm Hg. Of Goldmann tonometry measurements, when measured by a clinician, or in self-testing of non-diagnostically specific patients.

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2. Glaucoma sub groups yielded 82% within + and – 3 mm Hg. of Goldmann tonometry.

3. Home self-testing for a ten day period was undertaken in a group of controlled glaucoma patients as well as non-glaucoma cases. Over 2000 measurements were obtained. For two days measurements were taken every hour. For the remaining eight days pressure was measured 6 times a day. The standard deviation for readings taken 6 times daily yielded 0.7 mm Hg for 500 weekly readings.

4. In cases of advanced visual field loss [greater than 14dB on central 24-2 Humphrey], the phosphene tonometer yielded higher readings than Goldmann tonometry [mean difference of 7 mm Hg.]. In these cases a calibration correction is necessary for home monitoring, which compensates for the individual difference on a case by case basis.

5. Successive measurements with the phosphene tonometer yielded no statistically significant difference in repeat testing at 1, 3, 5, 8, 10 and 15 minutes.

6. There were no adverse effects evident in any of the studies that were evaluated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Bernard B. Fresco
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Re: K991840
Trade Name: FPT/Fresco Phosphene Tonometer
Regulatory Class: II
Regulation: 886.1930
Product Code: 86 HKY
Dated: May 25, 1999
Received: May 28, 1999

Dear Dr. Fresco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) K991840

DEVICE NAME Fresco Phosphene Tonometer and or Phosphene Tonometer and or FPT and or Eyelid Tonometer

INDICATIONS FOR USE

Clinical testing of intraocular pressure .
Self testing of intraocular pressure.
Home monitoring of intraocular pressure.
Screening studies, and outreach clinics.
For Glaucoma, Ocular hypertensive, and general population groups.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter-Use ✓
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Bruce Drum
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991840