JUN 17 1997 K970887

June 2, 1997
510(K) Notification
Paradigm Medical Industries, Inc., Blood Flow Analyzer

Enclosure 1.

510(K) Summary

Submitted by: Paradigm Medical Industries, Inc.
1772 West 2300 South
Salt Lake City, Utah 84119
(801) 977-8970

Contact Person: Richard Dirkson, Director of Regulatory Affairs

Prepared: June 2, 1997

- Trade Name - Blood Flow Analyzer
- Common Name - Tonometer and Accessories
- Classification Name - Tonometer and Accessories

Predicate Device: Ocular Blood Flow Laboratories (OBF) Model 115 Computer Tonometer System (K873422, SE date 11/02/87)

The OBF Labs' device was found equivalent to the Digilab OCVM-Ocular Cerebral Vascular Monitor manufactured by Digilab and the Alcon Applanation Pneumatograph manufactured by Alcon laboratories, Inc.

Device Description: A tonometer and accessories are devices intended to measure intraocular pressure by applying a known force on the globe of the eye to measure intraocular tension by applanation (applying a small flat disk to the cornea). Accessories for the device may include a tonometer calibrator or a tonograph recording system. We intend the device for use in the diagnosis of glaucoma.

Intended Use: We intend the device for use in the diagnosis of glaucoma.

Degree of Accuracy: When compared with Goldmann tonometery, the OBF Tonometer degree of accuracy is <3mmHg.

Device Specifications:

Power Supply	110-250 VAC, 50-60 Hz, maximum power consumption 40 W. Power supply is auto sensing. No voltage adjustments are required.
Sensor tips	25µ sensing film. Disposable to eliminate the risk of cross infection, designed to be used only once. Supplied in boxes of 50. Ultrasonically cleaned, then gamma irradiated.
Slit lamp adapters	A range of adapters is available to suit most leading makes including Haag Streitt, Zeiss, Nikon, etc.
Printers	Can be connected to a Seiko label plus printing system, any printer which supports Hewlett Packard PCL level 3+, or printers that are Cannon BJ10 compatible.
Database	A database system which runs under Microsoft Windows™ 3.1 or higher is supplied. It allows analysis of test results from the tonometer and monitoring of patient changes over time, advanced group analysis and search facilities making it a powerful tool for both day-to-day clinical use and research.
Keyboard	An 86-key keyboard, similar to laptop computers, is available which can be connected to the OBF system to allow entry of names and other patient information.
Carry case	an optional black ABS case is available to protect the Tonometer and its accessories while in transit.
Probe dynamic frequency response to intraocular pressure change	10 kHz
sampling frequency	200 Hz
Tonometer dimensions	280 x 240 x 100 mm, weight 4.5 kgs. (11 x 9.5 x 4 inches, 10 pounds)

SUBSTANTIAL EQUIVALENCE COMPARISON

Specification	OBF Model 115	Blood Flow Analyzer
Diagnostic Procedure	Non-invasive measurement of intraocular pressure and pulse amplitude with patient in position of sitting, standing, or supine.	Non-invasive measurement of intraocular pressure and pulse amplitude with patient in position of sitting, standing, or supine.
Sensor	Remote sensor probe with gas powered sensing element.	Remote sensor probe with gas powered sensing element.
Sensor tip material	Silicone rubber membrane	Polyurethane membrane
Data Display	Computer monitor provides numerical readout and graphical display.	Console monitor provides numerical readout and graphical display.
Data Recording	Dot Matrix Printer or laser printer or plotter with output for chart recorder (vertical axis=pressure [mmHg], horizontal axis=time [seconds]	Thermal Dot Matrix Printer or laser printer or plotter with output for chart recorder (vertical axis=pressure [mmHg], horizontal axis=time [seconds].
Data Storage	Computer memory system	Computer memory system, serial communications to a PC, floppy disk.
Gas	Physiologically inert dichlorodifluormethane	Filtered room air
Low gas indicator	red indicator lamp	N/A
Calibration	external calibration verifier standard (air gauge with plunger/silicone diaphragm system)	Calibration is performed once a month by the user inserting the probe into a tube and then pressing the calibration accept option - this then checks the pneumatics, etc. The user cannot alter the calibration.

References

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1997

Mr. Richard Dirkson
Director of Regulatory/Quality Affairs
Paradigm Medical Industries, Inc.
1772 West 2300 South
Salt Lake City, UT 84119

Re: K970887
Trade Name: Blood Flow Analyzer
Regulatory Class: II
Product Code: 86 HKY
Dated: June 2, 1997
Received: June 6, 1997

Dear Mr. Dirkson:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

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Statement of Indications for Use

510(k) number: unknown
Device name: Blood Flow Analyzer

Indications for use: A tonometer and accessories are devices intended to measure intraocular pressure by applying a known force on the globe of the eye to measure intraocular tension by applanation (applying a small flat disk to the cornea). Accessories for the device may include a tonometer calibrator or a tonograph recording system. We intend the device for use in the diagnosis of glaucoma.

Denise McCarthy
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K970887

Prescription Use ✓
(Per 21 CFR 801.109)