K943959

APR 10 1995

Section 2 - Safety and Efficacy Summary

MGC 1085 Ultimate E Plethysmograph with EuroPleth option

The hardware and software design of the 1085 Ultimate plethysmograph combines two previously cleared predicate devices, the 1085 plethysmograph (K852088) and the PF/Dx pulmonary function laboratory (K912906). The consolidation of these two predicate devices combines the separate features of each of them, with the exception of portability, into a single laboratory instrument. The 1085 Ultimate plethysmograph is substantially equivalent to its predecessor, the 1085 plethysmograph, and to other legally marketed competitive devices such as the SensorMedics 6200 Autobox D_L Automated Body Plethysmograph.

The indications for use of the 1085 Ultimate plethysmograph are identical to those for the previously identified devices; namely, the quantification of lung capacity and function. The 1085 plethysmograph is able to measure all lung volume subdivisions (using plethysmography to measure FRC), flow, resistance, conductance, and compliance. The PF/DX measures all lung subdivisions (using multibreath nitrogen washout to measure FRC), flow, lung diffusion, and maximal inspiratory and expiratory pressures. The 1085 Ultimate possesses all of the previously enumerated capabilities, including the option to measure airway resistance using the electronically compensated quiet breathing process.

There are several safety features inherent in the mechanical design of 1085 Ultimate plethysmograph. In fact, the 1085 Ultimate and the 1085 share the identical exterior chassis and wave form analyzer. The 1085 Ultimate builds on the safety features designed into the 1085 and adds a fully disposable patient circuit. Additionally, the 1085 Ultimate has received the UL-544 approval. For more detail concerning the hardware safety, please refer to the hardware hazard analysis contained in **Section 4 - Device Description**.

The software used to operate the 1085 Ultimate plethysmograph is identical to that used to control both the 1085 and the PF/Dx devices. All three devices use the same data and executable files as well as a common preprocessor (Wave Form Analyzer). Specific information with respect to software development, documentation and review of the software process, as well as bench test performance data is contained in **Section 8 - Software Validation and Verification**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

APR 10 1995

Re: K943259
MedGraphics 1085 Ultimate E
Plethysmograph
Dated: January 6, 1995
Received: January 10, 1995
Regulatory Class: II (TWO)
Product Code: 73 CCN

Ms. Kathryn A. Neumann
Medical Graphics Corporation
350 Oak Grove Parkway
St. Paul, Minnesota 55127-8599

Ms. Neumann:

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 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information

on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health