

8/2/99

K964235

**Exhibit 16 Summary of Safety & Effectiveness for
ABPM Mobil-o- Graph™ Blood Pressure Monitor, Model ABP Control**

ABPM Mobil-o- Graph™ Blood Pressure Monitor, Model ABP Control is a computerized blood pressure system designed for clinical applications to allow physicians or other health care providers to record, store, and playback patient data.

As such, this device is a Class II device, having Classification Name *ABPM Mobil-o- Graph™ Blood Pressure Monitor*, Model ABP Control.

Product Nomenclature	Classification Number	Regulation Number
Blood Pressure Computer	74DSK	870.1110
Non-Invasive Blood Pressure Measurement System	74DXN	870.1130

I.É.M. GmbH has determined that this device is substantially equivalent to a *predicate* medical device which is currently in commerce as the Ultralite Ambulatory Blood Pressure Monitor, Model SL 90202, manufactured by Space Labs, Incorporated of Redwood, Washington (determined substantially equivalent via K 855127). A determination of substantial equivalence is based upon:

Both the *ABPM Mobil-o- Graph™ Blood Pressure Monitor*, Model ABP Control and Ultralite Ambulatory Blood Pressure Monitor, Model SL 90202 are blood pressure monitors for clinical applications, to allow physicians or other health care providers to record, store, and playback patient data. Both devices use a computer program to display a pre-digitized patient image file. Both devices run under a computer operating system. Both devices use the computer operating system to access the displayed image.

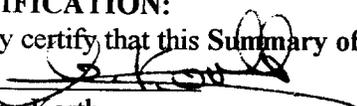
Both devices record, store, and playback patient data Both devices retain an electronically stored sample. Both act on that sample using mathematical computations. Both use a proprietary algorithm. Both use computer programming in a computer operating system.

The *ABPM Mobil-o- Graph™ Blood Pressure Monitor*, Model ABP Control has benefited from design, development, testing and production procedures that conform to Good Manufacturing Procedures. This device has performance characteristics substantially equivalent to its predicate device yet includes improvements to facilitate the various clinical applications for which it is intended.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. *I.É.M. GmbH* continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:

I hereby certify that this Summary of Safety and Effectiveness applies for the above indicated device.


 Mr. Uwe Korth
 Director, Product Services
I.É.M. GmbH
 Industrielle Entwicklung
 Medizintechnik und Vertriebsgesellschaft mbH
 Cockerillstraße 69
 D-52222 Stolberg



MAR - 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Industrielle Entwicklung Medizintechnik
und Vertriebsgesellschaft GmbH
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907

Re: K964235
Mobil-O-Graph™ Blood Pressure Monitor, Model ABP Control
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: February 5, 1999
Received: February 9, 1999

Dear Mr. Keen:

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 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). 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.

Page 2 - Mr. Richard Keen

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) 594-4648. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

From :

PHONE No. : 3292345

Mar.01 1999 5:46PM P02

510(K) Number (If known): K964235 ~~no 510(K) number assigned~~

Device Name: ABPM Mobil-o- Graph™ Blood Pressure Monitors, Model ABP Control

Indications for Use

This portable device, the *ABPM Mobil-o- Graph™* Blood Pressure Monitor manufactured by *I.E.M. GmbH* is an automated, microprocessor controlled blood pressure monitor which monitors, accumulates and stores: heart beat (rate) systolic and diastolic data of a individual adult patient (in the patient's environment) for a session which may last 24 to 48 hours.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K964235

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)