



AUG 14 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Detlef Grotheer  
Erich Jaeger GmbH  
LeibnizstraBe 7  
D-97204 Höchberg  
GERMANY

Re: K980876  
Asthma Monitor AM2  
Regulatory Class: II (Two)  
Product Code: 73 BZG  
Dated: July 10, 1998  
Received: July 13, 1998

Dear Mr. Grotheer:

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 (Pre-market 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 pre-market 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.

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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" (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/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

510(k) Number (if known): **K980876**  
Device Name: **ASTHMA MONOTOR AM2**

**Indications For Use:**

The Asthma Monitor AM2 from JAEGER is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever is a need of. The AM2 measures the flow during expiration serving for the calculation of further parameters as FEV1, FVC or FEF25-75.

The AM2 is used to monitor the respiratory status of human beings in the areas asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.

The patient is informed of the results by numeric values for selected parameters (e.g. PEF, FEV1). Furthermore a visual control unit, displayed as a kind of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.

The device saves the results of a measurement (always with date and time) automatically in an internal database. The memory capacity is designed to store up to 400 measurements. In addition, a questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM2 can be programmed with up to 12 questions, where the patient can select then from up to 7 different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS.

The AM2 is designed to replace ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM2 being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational medicine.

Caution: Federal law restricts this device to sale by or on the order of a physician.

June-26-98

Achim Schülke

Product Manager



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Lark W. Madon 8-12-98*

(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

Over-The-Counter

Prescription Use \_\_\_\_\_

Use \_\_\_\_\_

510(k) Number \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)