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AUG 6 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

Dr. Peter Gebhardt  
Manager, Approvals and Regulatory Affairs  
Drager Medizintechnik GmbH  
Moislinger Allee 53-55  
23542 Lubeck, Germany

Dear Mr. Gebhardt:

We are writing to you because on April 26-29, 1999, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving your anesthesia, intensive care ventilators, incubators and other medical devices.

Under a United States Federal law, The Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body (Section 201(h) of the Act).

The above-stated inspection revealed that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation of these devices are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. In legal terms, the products are adulterated within the meaning of section 501(h) of the Act, as follows:

1. **Failure to validate computer software used as part of the quality system for its intended use according to an established protocol as required by 21 CFR 820.70(i).** For example, the data in the Excel spreadsheet identified as a "Hit List" of top non-conforming components contains 16 record counts for Part number 8601618 DC converter failures compared to 18 record counts for Part number 860168 DC converter failures in the dbase database. The spreadsheet is used for management review of component suppliers for all components.
2. **Failure to include in the Device Master record, or refer to the location in the DMR, component specifications, as required by 21 CFR 820.181(a).** For example, electrical schematics, drawing and parts list for Part number 8601618 Drager custom DC converter are not maintained as part of the device master record for the Julian anesthesia system. The design engineering department maintains a set of drawings and a part number list for Part number 8601618 Drager custom DC converter from a component vendor that were not official nor controlled drawings from the Julian Device Master Record.

3. **Failure to verify or validate corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).** For example, the cooling fan used in Part number 860161B DC converter was concluded by the DC converter assembler as a potential cause for premature failure of the DC converter and replaced the type 612GMI fan with a type 612MI. R16 was reportedly moved to reduce heating in the area of C7 and increase the reliability of C7.
4. **Failure to maintain records of changes to documents as required by 21 CFR 820.40(b).** For example, Änderungsstandnachweis DCW-JULIAN lists changes, such as a new cooling fan or movement of resistor R27, with no documented change notice.
5. **Failure to establish and maintain procedures to investigate the cause of nonconformities relating to product processes and the quality system as required by 21 CFR 820.100(a)(2).** For example, the failure investigation documentation did not fully identify all failed components with regard to the failure of Part number 8601618 DC converter. Specifically, document titled Sondrrprüfung Fa. Elba dated 09.03.99 showed failures of Tr.1, T14 and T15. The failure of these components could not be explained without the failure of C7. C7 was not identified as a failed component.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. We have reviewed your response. Detailed comments on your response are enclosed.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

Given the serious nature of these violations of the Act, the Julian Anesthesia Machine manufactured by Drager Medizintechnik GmbH may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections have been verified, and you are notified that your corrections are adequate, your devices may resume entry into this country.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to:

James W. Eisele, Consumer Safety Officer  
Office of Compliance  
Division of Enforcement III (HFZ-343)  
Center for Devices and Radiological Health  
2094 Gaither Rd.  
Rockville, MD 20850

If you have any questions about the contents of this letter, please contact Mr. Eisele at the above address or at (301) 594-4659, or fax (301) 594-4672. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at (301) 443-6597, or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

Enclosure: As Stated