



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

97-PHI-40

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

|                                   |                     |
|-----------------------------------|---------------------|
| GEN.                              | SPEC.               |
| RELEASE                           |                     |
| F# _____                          | DATE <u>8/29/97</u> |
| Reviewed by: <u>R. C. Chen</u> CO |                     |

August 11, 1997

Mr. Michael A. Krupa  
President  
Precision Medical, Inc.  
300 Held Drive  
Northhampton, PA 18067

Dear Mr. Krupa:

On March 31 to May 20, 1997, Food and Drug Administration (FDA) Investigators, John S. Shea, and Valerie H. Wright conducted an inspection at your facility. The inspection revealed that your firm manufactures respiratory therapy devices, such as flowmeters and flow selectors.

These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), and as such are subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

At the conclusion of the inspection, an FDA-483 List of Inspectional Observations, was issued to, and discussed with you. On the FDA-483, your firm was cited for deviations from the Good Manufacturing Practice Regulations, with respect to both the Flow Selectors and flowmeters, and for your deficiencies associated with the Medical Device Reporting (MDR) Regulation.

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation, are not in conformance with the Current Good Manufacturing Practice (CGMP) Regulation, as specified in 21 CFR, Part 820, as follows:

Failure to complete investigations into your complaints [21 CFR §820.198(c)]. Your firm has failed to reply to user

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facilities involved in the complaints in order, to correct their understanding of the use of the Flow Selector. This would also be a violation of the Quality System Regulation, 21 CFR §820.198(e).

Failure to adequately investigate any failure of a device, to meet performance specifications after the device has been released for distribution, as required by 21 CFR §820.162. Your firm's testing of the [REDACTED] for the investigation of the [REDACTED] flowmeters was not conducted under similar conditions, or under the same controls as when the fires occurred in the clinical setting, therefore, possible causative agents and/or ignition factors have not been clearly identified for the events. This would also be a violation of the Quality System Regulation, 21 CFR §820.100(a)(1).

Failure of the device master record (DMR) to include specifications, including appropriate drawings, composition, formulation, and component specifications, as required by 21 CFR 820.181(a). Your firm's DMR is inadequate, because the individual parts of the flowmeter have separate history files, but these files are not cross-referenced to provide a history of the product as a whole. This would also be a violation of the Quality System Regulation, 21 CFR §820.181(a).

These devices are misbranded within the meaning of section 502(t)(2) of the Act, in that information was not provided to FDA, as required by the MDR Regulation, 21 CFR §803, as follows:

Failure to report that a device may have caused or contributed to a serious injury, as required by 21 CFR §803.50(a)(1). Your firm incorrectly reported an incident dated [REDACTED] at [REDACTED], as a malfunction. The incident, where a newborn had problems breathing and required mouth-to-mouth resuscitation, because the Flow Selector did not function properly due to operator user error, should have been reported as a serious injury.

Failure to conduct an investigation of each event and to evaluate the cause of the event, as required by 21 CFR §803.50(b)(2). Your firm's management copied information from the [REDACTED] complaint, rather than doing a follow-up at the facility to verify information and come to a conclusion of cause.

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Failure to contact user facilities to obtain complete information for user facility submitted reports, as well as failure to provide information to complete blocks "G" and "H" on the MedWatch Form for MDR reporting, as required by 21 CFR §803.50(b)(1) and (2), and 21 CFR §803.52(e) and (f). Your firm did not contact user facilities to obtain complete information in order to complete sections "G" and "H" on the MedWatch Form, for MDR events at [REDACTED], [REDACTED], [REDACTED], and [REDACTED], as was required per your own MDR procedures, specifically Part [REDACTED] of the Procedure Section of [REDACTED] Medical Device Reporting.

Additionally, your MDR procedure should be updated appropriately to reflect all aspects of the December 11, 1995, Final Rule. Specifically, 21 CFR §803.17(b)(3) requires that MDR procedures contain documentation and record keeping of any information that was evaluated for the purpose of preparing the submission of semiannual reports or certification.

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.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a later comprehensive follow-up inspection, and may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing with fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to the underlying systems problems necessary to assure that similar violations will not recur.

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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.

Your reply should be sent to the attention of Richard C. Cherry, Compliance Officer, at the address noted above.

Sincerely,



Diana J. Kolaitis  
District Director  
Philadelphia District

cc: Pennsylvania State Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104  
Attention: Robert E. Bastian, Director  
Division of Primary Care and  
Home Health Services

rcc