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VIA FEDERAL EXPRESSFood and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751WARNING LETTER

FLA-99-94

September 24, 1999

Tracy Thompson, President  
Critical Disposables, Inc.  
700 Bevier Road  
Sanford, Florida 34474

Dear Mr. Thompson:

We are writing to you because on August 16-20 & 23-24, 1999 FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving catheterization manifolds, angiographic syringes, and pressure lines (high and ultra high), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your 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 the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

QS Regulation/GMPs

1. Failure to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100 (a)(1). For example, reports of pressure lines bursting below specifications, complaints of manifold cracks and leaking, complaints of contamination in fluid path of several manifolds, increasing number of in-process rejects due to scrapes, and high number of rejects involving solvent bonding (Inspectional Observations-FDA 483, Items A-E).

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2. Failure to verify and/or validate corrective and preventive action to ensure that the action is effective and does not adversely affect the finished product as required by 21 CFR 820.100 (4). For example, corrective and preventive action taken to correct deficiencies noted in FDA 483, Items 1A-1E was not documented (FDA 483, Item #1F).
3. Failure of management with executive responsibility to ensure that the suitability and effectiveness of the quality system satisfies the established quality policy and objectives as required by 21 CFR 820.20(c). For example, numerous reported complaints and non-conformities were not adequately reviewed, investigated and corrected pursuant to your written procedure, DeRoyal Plastics Group Policy, Section 4.1 Management Responsibility (FDA 483, Item #4).
4. Failure to ensure that validated processes are performed by personnel, who are qualified by training to adequately perform their assigned responsibilities as required by 21 CFR 820.75(a)(1). For example, training of personnel to conduct manual processes such as visual inspections, solvent bonding and injection mold set-up is not determined by a relevant number of consecutive attempts that are proven to be successful (FDA 483, Item #5).
5. Failure to establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met as required by 21 CFR 820.70(g)(1). For example, no preventive maintenance was completed and documented for injection molds FDA 483, Item #6).
6. Failure to establish and maintain procedures to ensure that specified requirements for in-process products and components are met or controlled until required inspection or other verification tests are completed, received and documented as required by 21 CFR 820.80(c). For example, no in-process monitoring of High Pressure/Ultra High Pressure Lines is completed, monitoring by the corporate office is not provided for incorporation into the CAPA program, and the data is not compared to other months' data to determine trends in current reject rates. There also was a failure to document review of the Ultra High Pressure Lines for the need to submit a new 510(k) premarket notification (FDA 483, Item #7).

**DESIGN CONTROL REGULATIONS**

7. Failure of design plans to describe or reference the design and development activities, define responsibilities for implementation and identify and describe interfaces with different groups or activities that provide or result in, input to the design and development process as required by 21 CFR 820.30(b). For example, the design plan fails to contain or reference design reviews, design verification, design transfer, and interaction between the groups involved in the design process (FDA 483, Item #8B).
8. Failure to ensure that devices conform to defined user needs and intended uses, including testing under actual and simulated use conditions as required by 21 CFR 820.30(g). For example, multiple injections were not performed despite their use in clinical setting and the performance qualification testing does not indicate how user needs are considered and assessed (FDA 483, Item #8c).

**MEDICAL DEVICE REPORTING**

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to furnish material or information required by or under section 519 respecting the devices. These violations include, but are not limited to the following:

9. Failure to report or to obtain adequate information necessary to determine the MDR reportability of complaints related to malfunctions or failures that may cause serious injury (FDA 483, Item #s 2 & 3).

Your firm should also conduct and document a review of the Ultra High Pressure lines for submission to FDA of a 510(k) premarket notification.

The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to Henry D Richardson, Plant Manager, 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.

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We have received and reviewed your firm's responses to the Inspectional Observations (Form FDA 483) dated September 9 & 17, 1999 signed by Lisa Y.F. Perkins, Director of Quality Assurance and Regulatory Affairs. The responses were found to be inadequate because most procedures and corrective actions have not been implemented. Further, corrective actions require Design Control review prior to changes being made to a device or a manufacturing procedure. These activities also cannot be verified by the responses received. Your responses have been made part of the Florida District file.

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 awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,



Douglas D. Tolen  
Director, Florida District