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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

(CORRECTED COPY)

FLA-99-92

September 28, 1999

Mark D. Robinson, President
Medical Development Research, Inc.
2451 Enterprise Road
Clearwater, Florida 33763

Dear Mr. Robinson:

We are writing to you because on August 18-25, 1999 FDA Investigators Christine M. Humphrey and Michael W. Roosevelt collected information that revealed serious regulatory problems involving intraocular lenses, 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 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 review and evaluate all complaints to determine whether an investigation is necessary, maintain a record that includes the reason no investigation was made, and the name of the individual responsible for the decision not to investigate as required by 21 CFR 820.198(b). For example, 54 reported complaints specific to

"broken haptics" on both single and multi-piece lenses were not investigated and documented. (FDA 483, Item #4).

2. Failure to maintain records that demonstrate that each batch, lot, or unit of device meets in-process or finished device specifications as required by 21 CFR 820.80(c) & (d). For example, six Device History Records (DHR) failed to document all test results pursuant to your own procedures (FDA 483, Item #5).
3. Failure to validate and document all processes and/or off-the-shelf software used to operate and control equipment, which cannot be fully verified by subsequent inspection with a high degree of assurance, which is approved according to established procedures, as required by 21 CFR 820.75(a). For example, polishing validation fails to document adequate results for single and multi-piece lenses including polishing, tumbler speed, duration, and re-polishing of reworked lenses, off-the-shelf software use for the operation of the DAC lathe and to trend quality data related to nonconformances (FDA 483, Item #6 & #9).

DESIGN CONTROL REGULATIONS [21 CFR 820.30(i)]

4. Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications as required by 21 CFR 820.30(h). For example, review of your design control procedures, SOP 6007, (Revision A), dated March 25, 1999, revealed no procedure specific to design transfer to ensure that the design basis for the device is correctly translated into production methods and procedures.

This is a recurring observation which was listed on the Inspectional Observations (Form FDA 483) during the previous inspection dated March 19, 1999.

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:

5. Failure to maintain and implement written Medical Device Reporting procedures to ensure timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements as required by 21 CFR 803.17(a)(1). For example, review of complaints identified as 99-025 and 99-026 for lenses which were explanted were not adequately evaluated (FDA 483, Item #3).

6. Failure to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a serious injury, if the malfunction were to recur as required by 21 CFR 803.50(a)(2). For example, a minimum of two complaints identified as 99-025 and 99-026 were not reported to FDA (FDA 483, Item #3).

These are recurring observations which were listed on the Inspectional Observations (Form FDA 483) during the previous inspection dated March 19, 1999.

Several FDA 483 items related to your Investigational Device Exemption (IDE) were forwarded to CDRH Division of Bioresearch Monitoring for review and their response may support additional violations. These charges will be addressed under separate cover.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you 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 have received and reviewed your firm's responses to the Inspectional Observations (Form FDA 483) received on August 27, 1999, and signed by Maylene Dunham, General Manager, FDA Management Representative. 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,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is fluid and cursive, with a large loop under the 'D' and 'T'.

Douglas D. Tolen
Director, Florida
District