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Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

WARNING LETTER

FLA-99-62

May 3, 1999

Jane S. Rayhack, Owner  
Secretary/Treasurer  
Creative Medical Designs, Inc.  
13914 Shady Shores Drive  
Tampa, Florida 33613

Dear Ms. Rayhack:

We are writing to you because on February 17-18, 1999, FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving the Rayhack Ulnar Bone Plate and the Rayhack Radial Kienbock Bone Plate (Class II), 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 under section 201(h) of the Act because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the Rayhack Ulnar Bone Plate and the Rayhack Radial Kienbock Bone Plate 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 manufacturer, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

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1. Failure to document in the Device History Record (DHR) that each lot of finished devices meets acceptance criteria including the following records:
  - (a) finished testing or inspection was completed;
  - (b) the dates finished testing are performed;
  - (c) the results;
  - (d) the signature of the individual conducting the finished device testing; and
  - (e) where appropriate, the equipment used to conduct the finished device testing.

For example, there were no QA/QC test records available for 12 of [REDACTED] lots manufactured from January 1998 to December 1998. [21 CFR 820.80(d) and (e)]

2. Failure to establish and maintain procedures to control product that does not conform to specifications. For example, units from two lots were rejected, however, there was no evaluation or investigation of the defects documented. [21 CFR 820.90]
3. Failure to establish and maintain procedures for the identification, documentation, validation (or, where appropriate, verification), review, and approval of design changes before their implementation, as required by 21 CFR 820.30(I). For example, you have not established any written procedures for design changes and have not formally "approved" the design change made to the Ulnar and Kienbock Radial Bone Plates. No justification was provided for not performing design validation, and the design changes which were made to your Bone Plates were made in the absence of a formal written test procedure, a written statement of design objectives, a written test report, or formal approval of the design change.
4. Failure to establish and maintain procedures for verifying the device design to conform that device output meets

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design input requirements, and failure to include the method(s) and the individual(s) performing the verification in the design history file, as required by 21 CFR 820.30(f). For example, verification procedures have not been established and the test results, provided in an August 10, 1998, facsimile to you, did not include the method(s) used to perform the testing.

5. Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted and that an individual who does not have direct responsibility for the design state being reviewed is included in the design review. Failure to document the results of the design review in the design history file, including identification of the design, the date, and the individual(s) performing the review. For example, design review procedures have not been established and a formal and independent review of the design changes was not made or documented, as required by 21 CFR 820.30(e).
6. Failure to establish and maintain purchasing controls that include quality controls that must be met to assure that all products conform to specifications.
7. Failure to establish and maintain procedures to conduct and document quality audits both of contract suppliers and internally. [21 CFR 820.22]

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. 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 Inspectional Observations (FDA 483), issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing, distribution and quality assurance systems. Also, other Federal agencies are informed about the

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Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. We note that the Inspectional Observations (FDA 483) were annotated that your corrective actions would e made within 60-90 days. With your written response to this letter, please provide a timeline for each item when you believe corrections will be accomplished.

Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 555 Winderley Place, Ste. 200, Maitland, Florida 32751.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,



Douglas D. Tolen  
Director, Florida District