



VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-75

August 4, 2000

Douglas M. Coon, Owner  
Omega Medical Imaging, Inc.  
675 Hickman Circle  
Sanford, Florida 32771

Dear Mr. Coon:

We are writing to you because on July 11 & 12, 2000 FDA Investigator Ronald T. Weber inspected your facility and collected information that revealed serious regulatory problems involving your firm's manufacturing of cardiac and vascular imaging systems.

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm manufactures 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 devices that you manufacture 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. You have failed to exercise management responsibility to ensure that the quality system is adequate and effective as required by 21 CFR 820.20. For example, You failed to define, document, and implement management controls including a quality policy, management review, a quality plan and quality system procedures and instructions. The investigator also determined that you have procedures for conducting an internal audit but have failed to do so (FDA 483, Item #1).
2. You have failed to establish and maintain procedures to effectively implement adequate corrective and preventive action as required by 21 CFR 820.100. For example, you have not established and implemented adequate procedures for identifying, reviewing, and analyzing nonconforming product or other quality problems (FDA 483, Item #3).

**DESIGN CONTROL REGULATIONS [21 CFR 820.30(i)]**

3. You have failed to establish and maintain a design change procedure as required by 21 CFR 820.30(i) (FDA 483, Item #2).

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.

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. Additionally, no premarket submissions for Class III 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.

Douglas M. Coon  
Page 3  
August 4, 2000

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. Your response to the FDA 483 dated July 14, 2000 was received and found to be inadequate because it fails to provide any descriptions of your planned corrective actions and documentation covering those actions. Your response was made part of the Florida District file.

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, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal stroke at the end.

Emma R. Singleton  
Director, Florida District