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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Refer to: CFN 1122857

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4099

April 23, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

David Goodenough, Ph.D., President  
Institute for Radiological Image Sciences, Inc.  
3 Hillcrest Drive, Suite 202A  
Frederick, Maryland 21701

Dear Dr. Goodenough:

During a Food and Drug Administration (FDA) inspection of your firm located in Frederick, Maryland, on March 23 and 26, 1997, our Investigator determined that your firm manufactures the IRIS software program used for calculating bone density, which is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that this device is 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to maintain a complete Device Master Record (DMR). For example, the DMR did not include approved specifications and procedures for the manufacturing, components, quality assurance, packaging, labeling, and finished product release testing for the IRIS software program [21 CFR 820.181].
2. Failure to document and control changes made to the manufacturing specifications or source code to assure that the device conforms to its original design [21 CFR 820.100(a)(2)]. For example, you did not document the reason for a software upgrade from version 2.03 to 2.04.
3. Failure to maintain Device History Records for the validation and release testing of the finished device [21 CFR 820.160]. For example, no written records were available to show that testing was conducted to insure that the IRIS software program functioned properly prior to distribution.

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4. Failure to maintain written procedures to schedule and conduct periodic audits of the quality assurance program [21 CFR 820.20(b)]. For example, there were no audit procedures and no record that audits of the quality assurance program have been performed.
5. Failure to review, evaluate, and investigate complaints and to maintain complaint files [21 CFR 820.198]. For example, you received a complaint from [REDACTED], however, no records were available to document why an investigation was not required nor was the reply to the complainant documented.

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.

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 pre-market submissions for devices to which the GMP 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 do so 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, within 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 any underlying systems problems necessary to assure that similar violations will not recur. 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.

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Your response should be sent to Lori S. Lawless, Acting Compliance Officer, U.S. Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201.

Sincerely yours,



Carl E. Draper  
Acting Director, Baltimore District