



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

697 Original
Purged

HFI-35

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

November 21, 1997

WARNING LETTER

NWE -06-98W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Steven L. Nakashige,
President and Chief Operating Officer
Hologic, Inc.
590 Lincoln Street
Waltham, Massachusetts 02154

Dear Mr. Nakashige:

On October 1-2, 6-10, 10, 17, and 20, 1997, Inspector Lynne M. Dwyer and Investigator Anthony P. Costello conducted an inspection of your firm located in Waltham, Massachusetts.

[REDACTED]

During this inspection we determined that your firm manufactures [REDACTED] as well as x-ray bone densitometers. The [REDACTED] the QDR-1000 plus x-ray bone densitometer, and the QDR 4500 ACCLAIM series of x-ray bone densitometers are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that the QDR-1000 plus x-ray bone densitometer and the QDR 4500 ACCLAIM series of x-ray bone densitometers manufactured by your firm 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 manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP)/Quality System regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to adequately validate the [REDACTED] used in the manufacture of the QDR-1000 plus x-ray bone densitometer and the QDR 4500 ACCLAIM series of x-ray bone densitometers. For example, according to the validation protocol used for this [REDACTED] [REDACTED] "installation", "requirements", and "product performance" qualifications were to be performed. There are no records showing that any of these steps were performed during the validation of this [REDACTED].
2. Failure to document the evaluation of non-conforming product. For example, while x-ray controller board, [REDACTED] was being tested in accordance with [REDACTED], it was observed that the board failed two, separate, distinct steps of the test procedure. Neither of the evaluations of these failures were documented.
3. Failure to implement and document corrective and preventive actions when product non-conformances are detected. For example, there is no indication that any activities were conducted to investigate the cause of the product non-conformances discussed in #2 above, nor is there any indication that any actions were identified to correct and prevent the recurrence of such product non-conformances.
4. Failure to maintain adequate records of changes made to documents. For example, there are no records documenting the changes made to Revisions A through D of the [REDACTED] validation protocol, [REDACTED]. Revision C of this document, which is unsigned and undated, was used to validate the [REDACTED] [REDACTED] used in the manufacture of QDR-1000 plus x-ray bone densitometers and the QDR 4500 ACCLAIM series of x-ray bone densitometers.

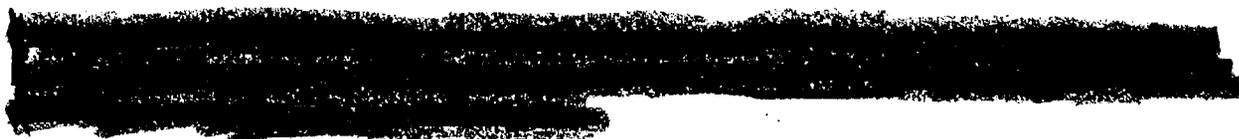
The change records covering the current version of this document, now identified as [REDACTED], Revision F, do not include an adequate description of the changes that are encompassed in the current document.

We acknowledge that you have submitted to this office a response concerning our Inspector's and Investigator's observations noted on the form FDA-483. Your response has not yet been reviewed. This response will be evaluated and communicated to you, however, you should not delay your response to this Warning Letter in the meantime.

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

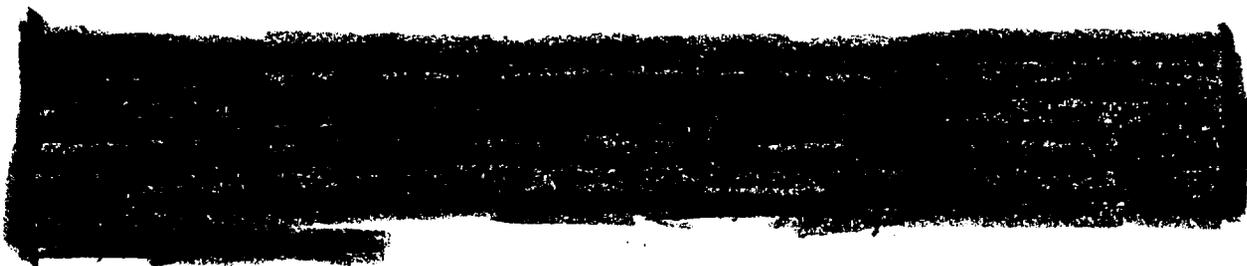
determined to be systems problems, you must promptly initiate permanent corrective actions.

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 premarket submissions for Class III devices to which the QSR 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 the violations identified in this Warning Letter. Failure to promptly correct these violations 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 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 fifteen working days, state the reason for the delay and the time within which the corrections will be completed.



Your response to this Warning Letter and subsequent certification statement should be sent to Alyson L. Saben, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,

John R. Marzilli
District Director
New England District Office