



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region d1945b

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6005

July 21, 1998

WARNING LETTER

Mr. Henry J. Tancredi, President
Imaging Sciences International, Inc.
941 Hamilton Avenue
Roebbling, New Jersey 08554

FILE NO: 98-NWJ-30
CFN: 2530069

Dear Mr. Tancredi:

We are writing to you because on May 11-13, 15, 18, 20, 1998, an investigator from our office collected information that revealed a serious regulatory problem involving the dental tomographic and panoramic x-ray machine product known as the CommCat IS-2000 Imaging System.

Under Section 201(h) of the Federal Food, Drug and Cosmetic Act (the "Act"), dental x-ray machines are defined as medical devices because they are used to diagnose or treat a medical condition or affect the structure or function of the body.

The CommCat IS-2000 Imaging System is adulterated within the meaning of section 501(h) of the Act, because your firm failed to adhere to the Quality System Regulations for Medical Devices as specified in Title 21, Code of Federal Regulations, Part 820, (21 CFR 820). The following deficiencies were documented at your firm:

- 1) Failure to meet the requirements for Complaint Handling as set forth in Section 820.198 in that:
 - a) There is no written procedure for complaint handling.
 - b) There is no documentation to show that complaints have been reviewed, evaluated and investigated, nor of decisions not to investigate these complaints.
 - c) Repair requests beyond the one-year warranty period are not reviewed to determine whether they are complaints, nor is information obtained by the software phone service documented and reviewed for potential complaints.

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- 2) Failure to meet the Quality System requirements for Management Responsibility as set forth in Section 820.20 in that:
 - a) A quality policy has not been defined, documented and implemented.
 - b) The responsibility and authority of the individuals in charge of areas such as mechanical design, production, and quality oversight have not been documented nor has a management representative been appointed to ensure that quality system requirements are effectively established and maintained.
 - c) Management review of these systems is not performed, nor are procedures established for conducting the reviews.
 - d) A quality plan has not been defined, documented and implemented.
- 3) Failure to meet the requirements for Acceptance Activities as set forth in Section 820.80 in that:
 - a) There are no written procedures for finished device testing and acceptance activities such as inspections, tests and verification activities for incoming components such as tubeheads and computer boards.
 - b) There is no documentation of the test results on safety features such as the radiation exposure alarm and the display of kVp and mA on the computer monitor. Also not documented is the length of time the device is required to cycle during finished product testing.
 - c) Failed test results and reworks are not documented in device history records.
 - d) There is no testing of the emergency stop switch and "stop chip".
- 4) Failure to meet the requirements for Corrective Action and Prevention as set forth in Section 820.100 in that:
 - a) There are no written procedures for implementing corrective and preventive action.
 - b) Processes, work operations, quality records and repair records are not analyzed to identify existing and potential causes of nonconforming product. For example, warranty repairs indicated eight out of eighteen units required repair in 1997 and three out of thirteen for 1998; however, no investigations were made.

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- 5) Failure to meet the requirements for Nonconforming Product as set forth in Section 820.90 in that:
 - a) Written procedures for the control of nonconforming product and nonconformity review and disposition have not been defined, documented, or implemented.
 - b) Written procedures for reworking have not been defined documented or implemented.

- 6) Failure to meet the requirements for the Device Master Record as set forth in Section 820.90 in that:
 - a) Three of ten machine assembly drawings were missing and included 2000-1415-000, exposure switch coil cord; 2000-1425, cassette wiring harness; 200011420-000, emergency stop switch.
 - b) Five of nine labels listed in the machine assembly drawing book were missing.
 - c) Drawing 2000-0002-0000, pluri-directional arm assembly has not been revised to reflect that part #5 has been replaced with part "M" and that three other parts are obsolete.
 - d) The Device Master Record lacks an approval signature and is not dated in accordance with section 820.40.

In addition to the above deficiencies it was observed that your firm failed to maintain written procedures for Medical Device Reporting as required in 21 CFR Part 803, Section 803.17.

The above identification of violations 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 Quality System regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. 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. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

We have reviewed your letter of May 22, 1998 written in response to the FDA-483, issued May 20, 1998. Your response to FDA 483 observations one, nine, ten, and eleven appears to be adequate and we will verify these corrective actions during our next inspection. The remaining observations, however, still require addressing.

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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.

Your response should be sent to Richard T. Trainor, Compliance Officer, Food and Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054.

Sincerely yours,

Edward H. Ellsworth
DOUGLAS ELLSWORTH
District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

RTT

cc: Edward J. Marandola, Vice President
Imaging Sciences International, Inc.
941 Hamilton Avenue
Roebing, New Jersey 08554

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Reviewed by RTT 7/23/98
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