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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

July 28, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Rosqvist
Senior Vice President
Ortho-Graphics, Inc.
807 East South Temple, Suite 100
Salt Lake City, Utah 84102

Ref. # - DEN-97-25

PURGED

Dear Mr. Rosqvist:

We are writing to you because on February 28 through March 3, 1997, Investigator James E. Moore from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the products known as the "██████████" and the "██████████" data management software systems, which are made and marketed by your firm. Please excuse our delay in corresponding with you.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your products for sale. The information you need to submit in order to obtain this clearance is available from our Center for Devices and Radiological Health. The FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

The above-stated inspection also revealed that the [REDACTED] and [REDACTED] systems 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) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish a device master record (21 CFR 820.181). For example, there is no documentation demonstrating the device specifications including the appropriate revisions, programming, finished product testing and software installation of your devices. This would also be a violation of the Quality System Regulation, 21 CFR 820.181.
2. Failure to establish a device history record in order to demonstrate that a device is manufactured in accordance with the device master record (21 CFR 820.184). For example, there is no documentation demonstrating the dates and quantity of devices manufactured, the quantity released for distribution and any control numbers used. This would also be a violation of the Quality System Regulation, 21 CFR 820.184.
3. Failure to establish an adequate quality assurance program (21 CFR 820.20). For example, your firm has failed to conduct planned and periodic audits to assure production records are reviewed; all components, manufacturing materials, in-process materials and finished devices are approved or rejected; quality assurance problems are identified and appropriate solutions are recommended and implemented and that all quality assurance checks are appropriate and adequate for their purpose. This would also be a violation of the Quality System Regulation, 21 CFR 820.22, 820.20 and 820.100.
4. Failure to establish written manufacturing specifications and processing procedures in order to assure that the device conforms to its original design or any approved changes in that design (21 CFR 820.100). For example, there is no documentation demonstrating the validation of software changes. This would also be a violation of the Quality System Regulation, 21 CFR 820.70.

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5. Inadequate complaint handling system (21 CFR 820.198) in that your firm has failed to follow your own procedures with regards to complaints. For example, numerous complaints were not fully documented to show the initial complaint information, any investigation or follow-up action. This would also be a violation of the Quality System Regulation, 21 CFR 820.198.

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.

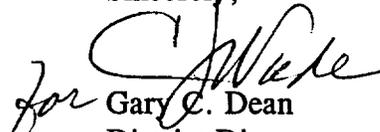
You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. No requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected. These actions include, but are 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.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to the Food and Drug Administration, Denver District Office, Attention: Regina A. Barrell, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Xuan T. Vo at (301) 594-4636 .

Sincerely,


for Gary C. Dean
District Director

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