



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

August 22, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Barry W. Hubbard
President/CEO
Ortho Development Corporation
12187 Business Park Drive
Draper, Utah 84020

Ref. # - DEN-01-46

Dear Mr. Hubbard:

An inspection of your firm located at 12187 Business Park Drive, Draper, Utah was conducted between June 5 - 8, 2001, by Investigator Lori A. Lahmann. This inspection determined that your firm manufactures various sterile, orthopedic hip, knee and spinal implants. These implants are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that these devices 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 Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

Inadequate corrective and preventative action (CAPA) procedures, as evidenced by:

- Not analyzing all significant sources of quality data, and using appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 CFR 820.100(a)(1). For example, your firm does not conduct failure investigations or determine the root cause of complaints of defective and returned devices which are received and documented on Return Material/Merchandise Reports (RMA's) or Product Incident Reports (PIR's) nor do you evaluate/investigate in-process or incoming raw material defects

documented on Material Review Reports (MRR's).

- Not investigating the cause of nonconformities relating to product, processes and the quality systems, as required by 21 CFR 820.100(a)(2). For example, RMA 01002, dated 1/23/01 documented a contour spinal system rod bender that was returned as "defective product." The disposition rationale is documented as "...scrap to evaluate root cause and corrective action and potential repair/rework activity..." However, there was no documented evidence that a root cause analysis or failure investigation was conducted. Also, several PIR's were reviewed and there was no evidence that a root cause determination was conducted. These PIR's include: # 012301-02, 030901-03, 032801-04, 032801-5 and 032801-06.

Failure to adequately evaluate and document complaints, as required by 21 CFR 820.198. Our inspection revealed that the PIR's are considered to be customer complaints and are handled via your sales/distribution personnel. RMA's are considered to be product returns, including defective goods that are handled by your customer service department. Review of your records indicated many of these PIR's and RMA's were not evaluated or handled as complaints.

Failure to establish written procedures in order to evaluate complaints to determine whether a complaint represents an event which is required to be reported to FDA under part 803, Medical Device Reporting (MDR), as required by 21 CFR 820.198(a)(3). Our inspection found that you did not have any written MDR procedures and that your firm had not evaluated PIR's or RMA's for MDR reportability. There was no evidence that these were evaluated for serious injury or the effect the device failure/malfunction had on the patient.

Failure to validate processes which cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75. For example, devices from five lots of implants were documented as having undergone a second dose of gamma radiation although your firm has not validated such resterilization.

Failure to conduct periodic management reviews to determine the suitability and effectiveness of the quality system, as required by 21 CFR 820.20(c). For example, your firm's procedure, "Management Review," Document Number SOP-000, Revision A, dated 10/11/99 requires, "...a review meeting will be held on a minimum of a quarterly basis to review the state of the business..." There was no evidence that your firm conducted quarterly management reviews between 6/24/00 and 1/4/01. Also, the current version of this procedure (Revision B) does not address the need to increase the frequency of reviews if quality deficiencies are disclosed.

Failure to conduct adequate design controls in that reviews of the design results were not conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e). For example, the procedure for the design project for the "Contour Spinal System" that began in January 1999 required design reviews to be conducted after each major stage in the device design development. However, the design review forms indicated that they were not all completed or signed off by either the Team Leader and/or Executive Management.

Additionally, your devices are also misbranded within the meaning of section 502(t)(2) of the Act in that your firm failed to submit information to the Food and Drug Administration (FDA) as required by the Medical Device Reporting (MDR) regulation, as specified in 21 CFR Part 803. Specifically, you failed to submit MDR reports to FDA as required by 21 CFR 803.50(a)(1) after receiving information that reasonably suggested that your B2 Bipolar Cup Hip System caused or contributed to serious injuries. MDR serious injury reports should have been submitted for Product Incident Report numbers: 080100-03 and 080100-04 because both events required medical intervention to preclude permanent impairment of a body function.

Written MDR reports for the above listed incidents should be submitted within 15 working days of receipt of this letter. If these reports cannot be submitted within that time period, you should provide this office with a response that indicates when the reports will be submitted. The MDR reports should reference this Warning Letter and be directed to:

Mrs. Victoria A. Schmid
Division of Surveillance Systems (HFZ-533)
Office of Surveillance and Biometrics
Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850

Your firm is required to submit a written report to FDA within ten working days of initiating either a product correction or removal that is intended to: (1) reduce a risk to the public health; or (2) remedy a violation of the Act which may present a risk to health. These reports will help FDA protect the public health by improving the agency's ability to evaluate device-related problems and to take prompt action against potentially dangerous devices.

Our records indicate your firm initiated a removal, as defined by 21 CFR Part 806, and did not submit the required report to our District Office. A recall of the B2 Bipolar Cup Hip System was conducted in February 2000, because the retaining ring had been inserted upside down. The failure to report this recall causes your product to be further misbranded within the meaning of Section 502(t)(2) of the Act. Within ten working days, please submit the information regarding this removal, as required by 21 CFR 806.10(c) to:

Mr. Don Bean, Recall Coordinator
Food and Drug Administration,
Denver District Office,
P. O. Box 25087
Denver, Colorado 80225-0087

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the regulations, as well as other requirements of the Act. Continued distribution of violative devices may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

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Federal agencies are advised of the issuance of all warning letters regarding medical devices so that they may take this information into account when considering the award of contracts.

You should notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: Regina A. Barrell, Compliance Officer. Please provide Ms. Barrell with a copy of each MDR report sent to Ms. Victoria Schmid.

Sincerely,


Thomas A. Allison
District Director