



DEPARTMENT OF HEALTH AND HUMAN SERVICES

242319

Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

August 11, 2003

VIA FEDERAL EXPRESS
NEXT DAY DELIVERY

Mr. F. Barry Bays, President
Wright Medical Technology, Inc.
5677 Airline Road
P.O. Box 100
Arlington, Tennessee 38002

Warning Letter No. 03-NSV-25

Dear Mr. Bays:

During an inspection of your firm on April 28-May 7, 2003, Food and Drug Administration (FDA) investigators determined that you manufacture and distribute the Transcend Hip System, a Ceramic-On-Ceramic Hip Articulation System. The inspection determined that [REDACTED] is the contract manufacturer for the Ceramic Acetabular Liner which is an accessory of the Transcend Hip System and is considered a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that the Transcend Hip System 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, or storing the device are not in conformance with the Quality System Regulation (QSR) for medical devices, set forth in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your firm commercially distributed the Transcend Hip System that had been manufactured without completing all the necessary process validation activities, as required by 21 CFR 820.75. More specifically, your firm commercially distributed acetabular liners as part of the Transcend Hip System that were manufactured as investigational devices. For example, your firm shipped a liner to [REDACTED] (part number [REDACTED] lot number [REDACTED]) on April 17, 2003. The liner was manufactured in July 1999 prior to the completion of process validation by your contract manufacturer for processes such as pressing-green-machining, HIP-sintering, lapping, polishing, grinding, laser-engraving, and cleaning.

In addition, the inspection also revealed that your firm did not adequately establish and maintain the requirements, including quality requirements, that must be met by suppliers, as required by 21 CFR 820.50(a). More specifically:

1. Your firm did not sufficiently evaluate your contract manufacturer [REDACTED] to ensure that documentation was available at [REDACTED] to show the supplier could consistently produce device in accordance with the designated specifications: and
2. Your firm's Purchasing Supplier Audit Checklist Procedure did not ensure that the:
 - a. inspection, measuring and test equipment at the supplier is suitable for its intended purpose and is capable of producing valid results;
 - b. production and process controls at the supplier are in accordance with specified requirements; and
 - c. processes at the supplier are validated when the results can not be fully verified by subsequent inspection and test.

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 the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes of the violations identified by the FDA.

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 request for Certificates to Foreign Governments will be approved until the violations related to the subject device have been corrected.

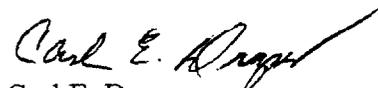
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (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 system problems necessary to assure that similar violations will not occur.

If corrective actions cannot be completed with fifteen (15) working days, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District