



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

M3124M

November 2, 1999

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CERTIFIED-RETURN RECEIPT REQUESTED

Ms. Patricia A. Roddy, Partner
Solo-Sled, LLC
8300 Providence Road
Ooltewah, TN 37363

Warning Letter - 00-NSV-02

Dear Ms. Roddy:

During an inspection of your firm located at 2413 Vance Avenue, Chattanooga, Tennessee on September 13-21, 1999 our investigators determined that you distribute a contract manufactured Class II radiographic film cassette holder device under the name of Solo-Sled. The inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (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 Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (CGMP) for Medical Device Regulations were superceded on June 1, 1997 by the Quality System Regulation.

The inspection revealed deviations from Part 820 including a failure to establish and maintain quality system requirements, failure to maintain a device master record, inadequate Quality Audit procedures, inadequate QSR training of firm's personnel, and a failure to sign and date written procedures.

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 may be symptomatic of serious underlying problems at your firm. You are responsible for investigating and determining the cause of the violations identified by the FDA.

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Federal agencies are advised of the issuing 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 Certificate for Product for Export will be approved until the GMP violations related to your Solo-Sled 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 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 (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 assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

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

Sincerely,



James E. Gamet

Director, New Orleans District

JEG/kl

Enclosure: 21 CFR Part 820

Cc: Robert J. LoTufo
Chief Manager
Lookout Industries
2710 Kanasita Drive
Hixson, TN 37343