

DEC 19 1996

Food and Drug Administration
2098 Galther Road
Rockville MD 20850VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Raymond C. C. Wadey
Managing Director
Micro-Precision Instruments Ltd.
Parkhill Drive
Frome, Somerset
ENGLAND BA11 2LE

Dear Mr. Wadey:

During an inspection of your firm located in Frome, Somerset, England, on August 2-5, 1996, our investigator determined that your firm manufactures silicone finger joint spacers. The Helal Finger Joint Spacers 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 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 investigate a critical device or component which does not meet its performance specifications and make a written record of the investigation, including conclusions and follow-up, as required by 21 CFR 820.161. For example, final product rejects are not identified and investigated to determine the source of the product failure.
2. Failure to implement specification control measures to assure that the design basis for the device and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100 (a)(1). For example, the processes have not been qualified to assure homogeneity or stability of the _____ prior to product _____
3. Failure to establish and implement written procedures for removing manufacturing materials, such as cleaning agents or other substances used on or in the manufacturing equipment or the device, from the device or limiting them to a specified amount that does not

adversely affect the device's fitness for use, and to document the removal or limitation of such manufacturing materials, as required by 21 CFR 820.60(d). For example, the _____ utilized to _____ e devices has not been qualified to assure that those _____ used _____ do not affect the device material.

4. Failure to have written procedures for performing planned and periodic audits of the quality assurance program, as required by 21 CFR 820.20(b). For example, there are no quality audit procedures/systems currently in-place to assure that the product/processes are in conformance with product specifications.
5. Failure of the device master record to be signed by a designated individual, as required by 21 CFR 820.181. For example, current SOPs and manufacturing procedures have not been signed/approved for official implementation.

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 FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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 premarket submissions for devices to which GMP deficiencies are reasonably related will be cleared until the violations 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 automatic detention of products manufactured.

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

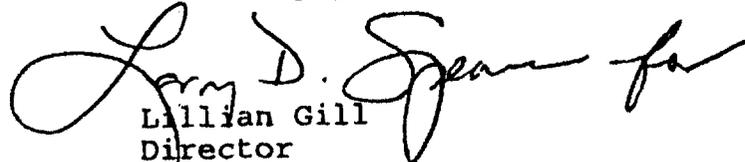
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corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Brenda Hayden
Interdisciplinary Scientist
Food and Drug Administration
2098 Gaither Road, HFZ-343
Rockville, Maryland 20850.

Sincerely yours,



Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

