



OCT 3 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Uwe G. Peck
Managing Director/Co-Owner
Normed Medizin-Technik GmbH
Ulrichstrasse 7
D-78532 Tuttlingen, Germany

Dear Mr. Peck:

During an inspection of your firm located in Tuttlingen, Germany on August 7, 1997, our investigator determined that your firm manufactures surgical instruments. These 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 current good manufacturing practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) regulation was superseded on June 1, 1997, by the Quality System Regulation. Since the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP's. We have received your response dated September 12, 1997, to the FDA 483 issued by the investigator following the inspection.

1. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria and are not released for distribution until the activities required in the device master record are completed, and the associated data and documentation is reviewed, as required by 21 CFR 820.80(d)(1) and (2). This would also be a deficiency under the GMP regulations 21 CFR 820.160. For example, [redacted] of [redacted] device history records revealed [redacted] distribution of Maxillo-Craniofacial distractor systems that were out of specification for the hardness test. This resulted in [redacted] distractors being shipped to consignees that did not meet the hardness test specifications.

Your September 12, 1997, response may be adequate. You state you have re-evaluated the standard for hardness testing of these devices and have instituted a new standard

for that test. The hardness value has been changed, a Process Change Notice issued, and an evaluation performed on devices after performing the hardness test with the new specification. The evaluation of the devices confirmed that the specification is now adequate. You also state that no ~~devices~~ devices is necessary since the acceptable range of hardness values is adequate to encompass those devices already distributed.

2. Failure to establish and maintain an adequate organization structure to ensure that devices are designed and produced in accordance with the requirements of this part including management with executive responsibility appointing and documenting such appointment of a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part, as required by 21 CFR 820.20(b)(3). This would also be a deficiency under the GMP regulations 21 CFR 820.20(a)(4). For example, it was determined that the erroneous heat treatment results were likely due to an inadequate specification rather than a malfunctioning instrument. After installation of the equipment, you selected a specification range for the hardness test loosely based on the DIN standard for stainless steel. You did not supplement this information by performing tests to determine a reasonable specification range for the product to allow some variation, but still ensure quality.

Your response may be adequate. As noted in number one above, you state that a new standard is established for the hardness test and an evaluation of the devices confirms the adequacy of the specification.

3. Failure of the device master record to include, or refer to the location of, for each type of device, device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications, as required by 21 CFR 820.181(a). This would also be a violation of the GMP regulations under 21 CFR 820.181(a). For example:
 - (a) The contract for the supplier of the Laster Retractors refers to the specifications contained in the Technical Documentation for the product. The Technical Documentation for the Laster Retractors is dated August 4, 1997. The most recent shipment of Laster Retractors was dated July 30, 1997 and found to be out of specifications.

- (b) The Technical Documentation for the Laster Retractors that was provided to the supplier references the wrong material. The documentation shows the material to be used as ~~XXXXXX~~ a non-existent standard for the required material. The correct material standard is

Your response may be adequate. You state that a new device master record, device history record, and supplier contract have been created to resolve this issue. Copies of both the master record and history record are provided with your response. The documents reference the correct specification and standard for the hardness of the retractors. The new supplier contract also has the correct standard for the retractors.

4. Failure of the device master record to include, or refer to the location of, for each type of device, quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used, as required by 21 CFR 820.181(c). This would also be a violation of the GMP regulations under 21 CFR 820.181(c). For example, there are no test procedures for how the hardness test is to be performed, specifically, which part of the distractor is to be tested. The hardness test results are dependent on the area of the retractor which is tested, because the hardness can vary within a single surgical instrument.

This issue was reported by the investigator in the Establishment Inspection Report, and not noted on the FDA 483. You must respond to this issue.

5. Failure to inspect, test, or otherwise verify as conforming to specified requirements incoming product, as required by 21 CFR 820.80(b). This would also be a violation of the GMP regulations in 21 CFR 820.80(a). For example, sample sizes reviewed for the incoming ~~XXXXXX~~ screw and plate components are out of compliance with DIN ~~XXXXXX~~ that is specified in the device master record. It is unclear in the history logs for one lot size of ~~XXXXXX~~ screws whether a total of ~~XXXXXX~~ samples were sampled, or whether ~~XXXXXX~~ samples were obtained ~~XXXXXX~~ times.

Your response may be adequate. You state that the individual responsible for the component sampling was on leave during the inspection, returning shortly thereafter. No other employees perform component sampling. The individual informed you that the sampling size was correct, that all ~~XXXXXX~~ components were manufactured from the same lot, therefore requiring a sample size of ~~XXXXXX~~ components. The ~~XXXXXX~~ components were obtained from the lot and spread

over the entire range of tests performed for inspections. Copies of the edited device history records are enclosed for supporting documentation.

6. Failure to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required in 21 CFR 820.25(b). For example:
 - a. Approximately five months after the installation of the hardness test method, an employee asked management which portion of the device was to be tested.
 - b. Based on a review of the history logs for sampling incoming components, the employees are not familiar with the sampling size, nor how to designate the samples to the different inspections.

Your response does not address these issues. The items were not noted on the FDA 483, but were discussed in the Establishment Inspection Report.

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 form FDA 483 issued at the close-out 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 Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

In order to facilitate the FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the CGMP requirements of the Quality System Regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's Chief Executive Officer (if other than yourself) that your firm has initiated or completed all corrections called for in the report. The enclosed guidance may be helpful in selecting an appropriate consultant.

The certification of audits and corrections should be submitted to this office by the following date:

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- Initial certification by an outside expert consultant no later than March 30, 1998.

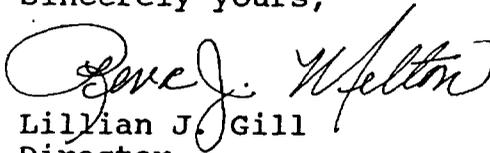
Given the serious nature of these violations of the Act, all devices manufactured by Normed Medizin-Technik GmbH, Ulrichstrasse 7, D-78532 Tuttlingen, Germany may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to have an outside consultant certify your compliance with the QS Regulation no later than March 30, 1998. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Shirk at the above address or at (301) 594-4595, ext. 162 or FAX (301) 594-4636.

Sincerely yours,

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

Enclosure: Selecting a Consultant?