



DEC 18 1998

WARNING LETTER
VIA FEDERAL EXPRESS

Tommy Hedberg, President
Atos Medical AB
Kraftgatan 8
S-242 22 Horby, SWEDEN

Dear Mr. Hedberg:

During an inspection of your firm located in Horby, Sweden, on September 16-22, 1998, our investigator determined that your firm manufactures an implantable voice prosthesis (Provox). This product is a device 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 their manufacture, packing, storage, or installation are not in conformity 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 implement corrective and preventive action to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). For example, the system that captures all quality data (including in-process testing data, component testing data, complaints, and returned products) has not been implemented. Also, this system had not been capable of identifying potential causes of nonconforming product, or other quality problems.
2. Failure to base sampling plans on a valid statistical rationale, as required by 21 CFR 820.250(b). For example, the number of loading tubes tested as part of a design change was not based on any statistical rationale. A material change and dimensional change were made to the loading tube component of the [REDACTED]. Additionally, during validation process there was no statistical rationale used for the number of tubes tested (Engineering Change 522).

3. Failure to establish and maintain procedures to adequately control environmental conditions where environment conditions could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, after routine maintenance is conducted in the clean room, no testing is conducted to assure that specifications for environmental conditions are being met.
4. Failure to verify and/or validate the device design, as required by 21 CFR 820.30(f) & (g). For example, there are no studies or research to ensure that the cleaning techniques listed on the label of the [REDACTED] are adequate to clean the device and not adversely affect its function or safety. Currently, the labeling recommends cleaning the voice prosthesis with [REDACTED] or [REDACTED] on daily basis to prevent potential Candida growth.

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

We acknowledge that you have submitted a response dated October 4, 1998, concerning our investigator's observations noted on the form FDA 483. It appears that the response is adequate, however, a follow-up inspection will be required, to assure that corrections have been implemented. To arrange for a mutually convenient time for the inspection, please contact Mr. Ronald L. Swann, at the address above or call the telephone numbers below.

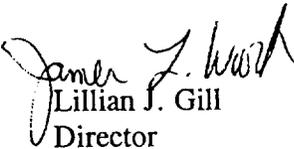
Until it has been determined that corrections are adequate, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and may result in the detention of your device(s) without physical examination upon entry into the United States.

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If you have any questions, please contact Mr. Ronald L. Swann, at (301) 594-4613 ext. 109 or FAX (301) 594-4638 or write to the letterhead address above.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian J. Gill". The signature is written in a cursive style with a large initial "L".

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