DEPARTMENT OF HEALTH AND HUMAN SERVICES

53532d

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

October 2, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-03-14838-0

Peter Botten, President
Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, Ohio 44130

Dear Mr. Botten:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on August 21-27, 2002, our investigator collected information that revealed serious regulatory problems involving medical image printers that are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), medical image printers are considered to be medical devices. The law requires that manufacturers of medical devices conform to the requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your 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, the manufacture, packing, storage, or installation are not in conformance with the requirements of the QSR as follows:

1. Failure to establish adequate management controls to ensure that an effective quality system has been established and maintained [21 CFR 820.20]. For example, management with executive responsibility has not established a quality policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a). In addition, your firm's Quality Manual procedures have not yet been approved and implemented.

2. Failure to conduct quality audits on a periodic basis in accordance with written procedures [21 CFR 820.22]. For example, procedures for conducting quality audits have not been established. In addition, your firm has been manufacturing medical devices for approximately six years and only one internal quality audit, dated December 12, 2001, has been conducted of your firm's quality system.

3. Failure to establish and maintain an adequate corrective and preventive action (CAPA) plan [21 CFR 820.100]. For example, procedures addressing documentation of CAPA activities have not been implemented.

4. Failure to establish and implement an adequate complaint handling program [21 CFR 820.198]. For example, your firm does not have an approved procedure for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a). In addition, there is no documentation that complaints received by your firm are evaluated to determine whether an investigation is necessary and no documentation as to who reviewed the complaints, as required by 21 CFR 820.198(b).

5. Failure to establish and maintain procedures to control the design of the device in order to ensure that the specified design requirements are met [21 CFR 820.30]. For example, your firm does not have written design control procedures that describe the design and development activities and that define responsibility for implementation. Specifically, there is no design plan for your firm's Horizon Printer.

6. Failure to ensure that only current and approved versions of documents are used in your firm's design and manufacturing of medical devices [21 CFR 820.40(a)]. For example, the procedures used by your firm's Corrective Action Team have not been approved.

7. Failure to establish and maintain procedures to ensure that device history records (DHR's) for each batch, lot, or unit are maintained in order to demonstrate that your firm's medical devices are manufactured in accordance with the device master record and the QSR [21 CFR 820.184].

In addition, your firm's medical devices are misbranded under Section 502(t) (2) of the Act. Specifically, your firm failed to develop and maintain written Medical Device Reporting (MDR) procedures, as specified in 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure 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 closeout of the FDA 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. You must also promptly initiate permanent corrective actions on your quality system.

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. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices 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. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We received your firm's letter of response to the Form FDA-483 that was issued to management on August 27, 2002. Your letter promised corrective action with regard to your firm's compliance with the QSR. The letter also contained preliminary quality control documents that

your firm is developing but has not yet approved. Not all of the actions you are taking appear to be adequate to correct the deficiencies noted by the FDA. For example, your firm's preliminary procedure for Corrective and Preventive Action does not address validating the corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device. In addition, your firm has not yet established procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that your firm's medical devices are manufactured in accordance with the device master record and the requirements of the QSR. Also, there is no indication that you have developed a design control plan and established a design history file for your firm's Horizon Printer.

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 prevent the recurrence of similar violations. 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 response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097.

Sincerely,

John W. Thorsky
Acting District Director
Cincinnati District