DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

g42058

AUG 13 2003

WARNING LETTER

VIA FEDERAL EXPRESS

Clifton E. Barker
Part Owner/Sales & Marketing Manager
Cardio Design Pty. Ltd.
8/9 Packard Ave.
Castle Hill, NSW 2154, Australia

Re: Peritron Model 9300A with Anal Sensor and Model 9300V with Vaginal Sensor

Dear Mr. Barker:

On March 10-11, 2003, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility, and determined that your firm manufactures the Peritron Model 9300A with Anal Sensor and Model 9300V with Vaginal Sensor. These products are medical devices under the Federal Food, Drug, and Cosmetic Act (the Act), because they are intended for use in diagnosing or treating a medical condition or to affect the structure or a function of the body (section 201(h) of 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, the manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, as specified in Title 21 of the Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). Specifically, the following design control

procedures have not been established: design plan, design inputs, design outputs, design reviews, design verification/validation, design transfer, design changes and design history file, as required by 21 CFR 820.30(i). The quality manual part QM 4.0, Design Controls, indicates design controls are not applicable to the perineometer. This is a class II medical device requiring design controls.

2. Failure to implement management review procedures for conducting and documenting these reviews, as required by 21 CFR 820.20. Specifically, Management Review Procedure, S.O.P. No. 1.4, dated 18-8-97, requires a 6-month review of operations. These biannual reviews are not conducted.

3. Failure to conduct quality audits in accordance with the firm's internal procedures to assure that the quality system is in compliance with the established quality system requirements, as required by 21 CFR 820.22. Audits have not been performed.

4. Failure to maintain device history records, as required by 21 CFR 820.184. The following vaginal sensor assembly batch records 2030, 2052, and 02-006 used in the finished assembly of the following Peritron lots: 2054, 2041, 2032, 2029, 2026, and 2015; were not completed in accordance with established procedures.

Additionally, the above-stated inspection revealed that your device is misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information required by or under section 519 concerning the device and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Specifically, you failed to develop, maintain and implement written MDR procedures. While you have complaint handling procedures (S.O.P. 14.2), management was not familiar with the MDR regulation requiring manufacturers to submit reports to FDA concerning serious injuries or deaths that are attributable to the use of a medical device, pursuant to section 519(b)(1) of the Act.

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 close 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, which may include the refused entry of your affected products until the corrections are completed.

Please notify this office in writing within fifteen (15) working days as to the specific steps you have taken, or intend to take, to prevent the recurrence of similar violations. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

Please address your response to Paul Tilton, Chief, OB/Gyn, Gastroenterology, and Urology Devices Branch, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, 2098 Gaither Road, Rockville, Maryland 20850 USA.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Patricia L. Jahnes at the above address or at (301) 594-4639 or FAX (301) 594-4609.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health