TO: William H. Dippel, Vice President, Operations

FROM: Conceptus, Inc.

CITY, STATE, ZIP CODE, COUNTRY: San Carlos, CA 94070

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Not all data from quality data sources are analyzed to identify existing and potential causes of nonconforming product and other quality problems.

Specifically, during a review of Lot History Reports (LHRs) for the manufacture of the Essure Permanent Birth Control System, two Lot History Records showed rejected raw materials and/or subassemblies hand-written on the Work Order Picklist. This information/data was not documented on Page 2 of 3 of the QAF-2335 (Quality Assurance Form) which is used to track and trend in-process data.

Examples are:

- LHR (b) (4) shows (b) (4) Inner/Outer Coil Subassemblies rejected (hand-written) on the Work Order Picklist, but not document on Page 2 of 3 of LHR: Essure Sterile 2-Device (b) (4)
- LHR (b) (4) shows (b) (4) Inner/Outer Coil subassemblies rejected (hand-written) on the Work Order Picklist, but not document on Page 2 of 3 of LHR: Essure Sterile 2-Device (b) (4)

OBSERVATION 2

Procedures were not followed for the control of products that do not conform to specifications.

Specifically, your procedure, SOP-00383, "NONCONFORMING MATERIAL REVIEW", for handling nonconforming materials defines that a nonconforming material under Section 3.0 as (b) (4) (b) (4) "Your SOP also states that this procedures is to be used for (b) (4) (b) (4)

A review of Lot History Records (LHRs) revealed that raw materials and sub-assemblies (i.e., Inner/Outer Coil Sub-
assemblies) were being rejected during manufacturing of the Essure Permanent Birth Control device, but no Material Review Report(s) were initiated/generated for these rejects.

* DATES OF INSPECTION:  06/25/2003(Wed), 06/26/2003(Thur), 06/30/2003(Mon), 07/01/2003(Tue), 07/03/2003(Thur), 07/07/2003(Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Mark E. Chan, Investigator