SUMMARY OF FINDINGS

The firm, Conceptus Inc., applied for a device manufacturing license and was assigned pending license number 45136. The firm is a manufacturer of an implantable Class III medical device, specifically the Essure System for Permanent Birth Control.

A two item Notice of Violation (NOV) was issued during the pre-license inspection by the California Department of Public Health for failure to obtain a valid license from the department prior to manufacturing and distributing medical devices and failure to maintain the procedure Inventory Transfer. The violations were adequately corrected by June 11, 2008.

Recommendations: It was recommended that the device manufacturing license be issued for Conceptus, Inc. located at 331 East Evelyn Avenue, Mountain View, CA 94041.

INSPECTION OVERVIEW

Inspection date: This inspection was conducted on June 10-11, 2008.

Purpose: The inspection was conducted in response to a Medical Device License Application dated 12/05/05 and signed by Edward Sinclair. The inspection was pursuant to HSC 111635 that states "Prior to issuing a license required by Section 111615, the department shall inspect each place of business." This was a relocation inspection, the prior location at 1021 Howard Avenue in San Carlos, CA (license #62105) was licensed with department from 1994 to 2005.

Scope of Inspection: The Quality System Inspection Technique (QSIT) was used as guidance for this inspection focusing on Management Controls, Design Controls, Corrective and Preventive Actions, and Production and Process Controls.

Type of firm/Products: The firm was a corporation registered with the FDA, #2951250, and their Class III Essure System for Permanent Birth Control was listed. They held the following PMA:

- P020014, Essure System for Permanent Birth Control on November 4, 2002.

Supplement 18, the most recent PMA supplement submitted by Conceptus had been acknowledged on 05/22/08 by the FDA. In #18, the firm was seeking approval to terminate their post-approval study early. They reportedly had demonstrated adequate bilateral placement success for the Essure device, and did not feel adding more patients to the study would be beneficial.

The device was a micro-insert coil intertwined with PET fibers attached to a delivery system (introducer, delivery catheter, delivery wire). A doctor placed the coil at the uterine-fallopian tube junction, where its coating caused it to be attached to the tube. An Essure kit contained two...
devices, so the doctor would place a coil at both uterine-fallopian tube junctions. Over the weeks following the implants, a natural barrier should form around the insert. Three months following the procedure, the patient would undergo an x-ray to determine the barrier had effectively formed. The device was single use and sterile with a shelf-life of 24 months.

Ownership/history of firm:

The corporation was founded in the 1990's to help facilitate pregnancy. The original device did not go to market and now they manufacture a birth control device. Conceptus produced between 4,000 to 5,000 Essure kits per month, and distributed them domestically, in Canada, Australia, and the European Union.

The President and CEO Mark Sieczkarek was the most responsible person on site. See Exhibit A for the firm's organizational chart. The company had been at this site since December 2005, and it occupied approximately 50,000 square feet. See for the facility's floor plan. Conceptus had approximately 230 employees, mostly in sales, while 100 employees worked at this facility. They perform research and development, complaints, CAPAs and distribution functions at this site. Assembling, packaging and labeling were contracted out.

Individual(s) Contacted During the Inspection: Edward Sinclair was no longer with the company. The inspection contact was Henry Bishop, Quality Manager. He was cooperative in scheduling and providing documents during the inspection. Others participating in the inspection included:

Edward Yu, Director of Clinical Research and Regulatory Affairs
Tarhan Kayihan, Regulatory Compliance Engineer
Rob McCarthy, Director of Operations
Rachelle Acuna-Narvaez, Regulatory Affairs Associate
Shakil Ahmed, Senior Product Surveillance Engineer
Rich Suggs, Logistics Manager
Charan Singh, Associate Quality Engineer
Mark Pfirman, Senior Quality Engineer
Murray Mergone, Facilities Manager
Harpreet Singh, Senior Quality Engineer

All correspondence should be sent to:

Edward Yu
Director of Clinical Research and Regulatory Affairs
331 East Evelyn Ave
Mountain View, CA 94041

Previous licensing/inspection background: The firm was inspected by the department in 1994 at its former location. They were last inspected by FDA September 21-22, 2005 with no report of observations (483) issued.

California Department of Public Health
Medical Device Safety Section

Food and Drug Branch
National Standards Authority of Ireland (NSAI) had certified their quality system. They have CE Mark from NSAI.

AREAS INSPECTED/NONCONFORMANCY DISCUSSION

Management Controls

The firm had established and implemented procedures for this system. Henry Bishop had been appointed the firm's management representative. The following documents were reviewed and appeared adequate:

- Management Review, SOP 01104 Rev. N
- Management Review, Attendance and Agenda dated 10/17/06 and 11/09/07
- Internal Audit, SOP 00415 Rev. Z
- 6/2/08-6/6/08 Audit Summary
- Employee Training, SOP 00404
- Sample of four employee training records

No deficiencies were noted.

Design Controls

Design Controls were not a large focus of this inspection. The firm had established and implemented procedures for this system. The following were reviewed:

- Product Development Process, SOP 00799 Rev. R
- Risk Analysis, SOP 1830 Rev. H
- Annual sterilization validation, VR-2982 Rev. O, dated 7/20/07-7/23/07
- Design FMEA for ESS305 dated 01/05/07

No deficiencies were noted.

Corrective and Preventative Actions (CAPA)

The firm had established procedure and forms for this system. The following were reviewed and appeared adequate:

- Corrective & Preventive Action, SOP 00935 Rev. R
- Product Return, Complaint Handling and Reporting, SOP 1630 Rev. W
- Product Recall, SOP 01045 Rev. H
- Material Identification and Traceability Policy, SOP 3093 Rev. A
- CAPA, complaint, MDR logs
The firm had 1,587 complaints since the beginning of 2008, 15 CAPAs since 2006, and 12 MDRs since 2007. They’ve had no recalls. A sample of CAPAs, MDRs and complaints were reviewed. All appeared well documented, investigated to root cause, and adequately trended.

No deficiencies were noted, but better documentation of CAPA verification and validation activities for ease of explanation was discussed with the firm.

Production and Process Controls

Conceptus used a contract manufacturer for assembly of the Essure device. R&D, complaints and CAPAs, and distribution were the only in-house functions. A tour of the facility was conducted and the following were reviewed:

- Good Documentation Practices, SOP 00370 Rev. G
- Engineering Change Order Procedure, SOP 00399 Rev. G
- Essure Demo Assembly, R2688
- Deployment and Release of Micro-Insert Test, R2621
- Essure Delivery System Tensile Test Method, R2685
- Demo Packaging, R1882
- Sterile Load Control, SOP 01026 Rev. T
- Line Clearance, SOP 00922 Rev. K
- Incoming Inspection, SOP 00384, Rev. W
- Nonconforming Material Review, SOP 00383 Rev. V
- Supplier Selection, Approval and Monitoring, SOP 00739 rev. V
- Approved Supplier List
- Supplier files: [redacted] and [redacted]
- [redacted] Supplier Agreement (See Exhibit C)
- Environmental Monitoring of the Controlled Environment Room, SOP 00928, Rev AD
- CER testing dated 03/11/08 and 09/17/07 (CER was not used in production/R&D only)
- Calibration Procedure, SOP 00379 Rev. S
- Calibration log and two equipment files

Supplier [redacted] assembled the devices and shipped the devices to [redacted] in [redacted]. [redacted] shipped the sterilized devices to Conceptus. Conceptus reviewed the products certifications and performed incoming inspection on a sample of kits (AQL of 1.0), and then shipped accepted materials. The firm estimated that by December 2008, [redacted] will ship only the sample devices to Conceptus for inspection and send the devices to [redacted] in [redacted]. [redacted] would distribute the devices following Conceptus’s approval of the lot based on the samples they received.

No deficiencies were noted in the above.

One violation was noted for Inventory Transfer, SOP 00454 Rev. Y (See Exhibit D) because it was the procedure from their old facility and was not the procedure being used at the current facility. The firm provided adequate corrections on June 11, 2008 (See Exhibit E).