P020014/R21 C1



Conceptus

June 13, 2008

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: **ESS305 Post-Approval Study: 12 month interim report**
PMA P020014, Report #21
Essure® System for Permanent Birth Control ESS305

To Whom It May Concern:

In accordance with 21 CFR 822, Conceptus is submitting three copies of the 12-month interim report on the ESS305 Post-Approval Study.

The information contained in this 12-month interim report on the ESS305 Post-Approval Study is considered confidential and Conceptus therefore requests protection of this information in accordance with 18 USC 1905, 21 USC 331(I), 5 USC 552.

Please let me know if you have any questions or need additional information. I can be reached by phone at (650) 962-4078, by fax at (650) 962-5194, or by email at rachelle_acuna-narvaez@conceptus.com.

Sincerely,

Rachelle Acuña-Narvaez

Rachelle Acuña-Narvaez
Regulatory Affairs Associate

Conceptus, Inc.
331 East Evelyn Avenue
Mountain View, CA 94041 USA
Main Number: (650) 962-4000

P020044/R21 C1

Conceptus®

# ESS305 POST-APPROVAL STUDY

*12-Month Interim Report*



Data current to May 31, 2008

**ESS305 POST-APPROVAL STUDY**
*12-Month Interim Report*

## Table of Contents

# SECTION 1
# GENERAL INFORMATION

## Sponsor Information

*Name:* Conceptus, Inc.
*Address:* 331 E. Evelyn Avenue
Mountain View, CA 94041 USA
*Establishment Registration Number:* 2951250

*Contact Person:* Rachelle Acuña-Narvaez
*Telephone:* 650-962-4078
*Fax:* 650-962-5194
*e-mail address:* rachelle_acuna-narvaez@conceptus.com

## Product Information

*Product Name:* Essure Permanent Birth Control System
*Model Number:* ESS305
*Application Number:* P020014 – S012
*Date of PMA approval:* 06/15/2007

# SECTION 2
# SUBMISSION INFORMATION

*Date of Submission:* June 13, 2007

*Data included in this submission:* Clinical Study Data

*Type of Submission:* Twelve Month Interim Post-Approval Study Status Report

*Post-Approval Study Status:* Study Over-Due

# SECTION 3
# STUDY INFORMATION

## Purpose of the Study

The Essure System is comprised of a micro-insert attached to a delivery wire, held in the wound down position by a release catheter. The entire assembly is sheathed within a delivery catheter. This system is attached to a handle that facilitates micro-insert delivery and deployment. The Essure System was initially approved by the Food and Drug Administration ("FDA") for commercial use on November 4, 2002 under Pre-Market Application P020014.

Conceptus made several modifications to the ESS205 Essure System to improve usability of the delivery system. The ESS305 System has been subjected to bench testing to demonstrate its comparability to the existing ESS205 System. The results of this bench testing were used to support a Pre-Market Application Supplement (#P020014/S12) and submitted to the FDA. As a Condition of Approval, FDA requested that Conceptus conduct a post-approval clinical study to evaluate bilateral placement rates of the micro-insert for newly trained and experienced physicians.

The objectives of this post-approval clinical study are to determine the following:

- Bilateral placement of the ESS305 micro-insert at first attempt;
- Comparison of bilateral placement success between Newly Trained physicians and Experienced physicians;
- Identification of factors predictive of failure to achieve bilateral placement of the ESS305 micro-insert at first attempt;
- Evaluation of aspects of the ESS305 design that may impact bilateral placement rate;
- Hysteroscopy time to perform the procedure;
- Adverse device effects; and
- Adverse procedure events.

The data will be used to evaluate training procedures and update labeling as required.

## Investigator Enrollment

In order to determine the effectiveness of the ESS305 physician training, awareness, training materials, and labeling, the study will compare bilateral placement rates in (b)(4) newly trained physicians with (b)(4) physicians experienced in Essure micro-insert placement (i.e., experienced using the previous ESS205 device).

(b)(4) alternates) newly trained physicians in (b)(4) in the United States who complete the (b)(4) of the training program and (b)(4) have been or will be asked to participate in

this study. (b)(4) newly trained physicians have agreed to participate thus far. (b)(4) of these newly trained physicians are still awaiting IRB approval. (b)(4) other newly trained physicians have not yet submitted all of the materials necessary to become an investigator. (b)(4) more newly trained physicians may be recruited to the study.

(b)(4) experienced physicians in (b)(4) in the United States who have previously completed the Essure training program and (b)(4) with at least (b)(4) have agreed to participate in the study. (b)(4) of those experienced physicians is still awaiting IRB approval. (b)(4) more experienced physicians may be recruited as alternates to the study.

Investigator enrollment in this study is limited to no more than (b)(4) physicians from any (b)(4) and no more than (b)(4) newly trained physicians and/or (b)(4) experienced physicians from any (b)(4). In addition, no more than (b)(4) of the physicians will represent (b)(4).

**Patient Population**

The patient population will consist of a maximum of 860 women who agree to undergo the Essure Procedure prior to enrollment in the study. Once a woman who is scheduled to undergo the Essure Procedure consents to participate in the study, the investigator will collect demographic and micro-insert placement data. An adjusted placement rate will be calculated for those women in whom an Essure System is placed through the operating channel of the hysteroscope.

**Original Timeline**

As noted in Table 2(a) below, the original timeline anticipated initial site enrollment starting in July 2007. Table 2(b) below shows the original estimate of patient and investigator enrollment.

Table 2(a): Estimated timeline of post approval study

| Clinical Study Milestone | Expected Completion Date |
|---|---|
| Initial Site Enrollment with IRB approval: | July 2007 |
| Initial Patient Enrollment: | August 2007 |
| | |
| 86th Site Enrolled with IRB approval (~6 months): | January 2008 |
| 860th Patient Enrolled (~7 months): | August 2008 |
| | |
| Final report prepared: | November 2008 |
| Final report submitted to FDA: | December 2008 |

Table 2(b): Expected number of Investigators and study subjects enrolled by month

| Enrollment Milestone Date | # of Investigators enrolled (cumulative), | # of Patients enrolled (cumulative) |
|---|---|---|
| **2007** | | |
| July | (b)(4) | |
| August | | |
| September | | |
| October | | |
| November | | |
| December | | |
| **2008** | | |
| January | | |
| February | | |
| March | | |
| April | | |
| May | | |
| June | | |
| July | | |

**Revised Timeline**

Conceptus submitted a revised timeline in PMA Report (b)(4) ESS305 Post Approval Study Protocol (b)(4) (b)(4). The timeline submitted in that amendment is shown again below for reference purposes.

Table 3(a): Revised timeline of post approval study

| **Clinical Study Milestone** | **Expected Completion Date** |
|---|---|
| Initial Site Enrollment with IRB approval | August 2007 |
| 86th Site Enrolled with IRB approval | August 2008 |
| | |
| Initial Patient Enrollment | September 2007 |
| 100th Patient Enrolled | December 2007 |
| 200th Patient Enrolled | February 2008 |
| 400th Patient Enrolled | May 2008 |
| 600th Patient Enrolled | December 2008 |
| 860th Patient Enrolled | October 2009 |
| | |
| Final report prepared | November 2009 |
| Final report submitted to FDA | December 2009 |

Table 3(b): Expected number of study subjects and investigators by month

| Date | Expected # of Investigators enrolled (cumulative) | Expected # of Patients enrolled (cumulative) |
|---|---|---|
| (b)(4) | | |

* Physician Enrollment Complete
** Patient Enrollment Complete

**Study Schedule**

(b)(4)

The delay in patient enrollment is partially tied to the delay in investigator enrollment. It may also be related to the fact that Essure sales were lower than expected in the first part of the year, and, clinical study enrollment is expected to follow commercial use of Essure. Physicians have postulated that the early slowness was due to a combination of a greater proliferation of higher deductible Health Care plans, resulting in patients delaying elective procedures until their deductibles are satisfied, and the broader economic challenges in the economy. Conceptus expects to see patient enrollment increase in the coming months when the remainder of the

(b)(4)

**Unaudited Data**

| Number of patients enrolled | Number of successful bilateral placement procedures | Number of placement procedures resulting in unilateral placement | Number of unsuccessful placement procedures | Number of Non-attempts |
|---|---|---|---|---|
| (b)(4) | | | | |

**Unanticipated Device Effects**

No unanticipated device effects have been observed during the period from study initiation through May 31, 2008.

**Adverse Events**

Two adverse events have been reported during the period from study initiation through May 31, 2008. One patient suffered a vaso-vagal reaction during the procedure; the procedure was aborted and the patient treated, then rescheduled for another procedure. The second patient experienced vaginal bleeding starting on the day of her procedure and lasting for approximately a month, which the physician believed was related to Depo-Provera which was prescribed shortly prior to the procedure.

**Protocol Deviations**

Deviations to the study protocol included:

(b)(4)