P020014/R15

Conceptus®

December 13, 2007

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: 6 month interim report**
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 6-month interim report on the ESS305 Post-Approval Study.

The information contained in this 6-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

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ESS305 POST-APPROVAL STUDY

6-Month Interim Report

Data current to November 30, 2007

ESS305 POST-APPROVAL STUDY
6-Month Interim Report

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SECTION 1
GENERAL INFORMATION

Sponsor Information

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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: December 13, 2007

Data included in this submission: Clinical Study Data

Type of Submission: Six 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 newly trained physicians with physicians experienced in Essure micro-insert placement (i.e., experienced using the previous ESS205 device).

(b)(4) newly trained physicians in (b)(4) in the United States who complete the (b)(4) of the training program and (b)(4) (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)

experienced physicians in (b)(4) in the United States who have previously completed the Essure training program and have (b)(4) with at least (b)(4) (b)(4) have agreed to participate in the study. (b)(4) more experienced physicians will be recruited ((b)(4) 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) (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 for those women in whom an Essure System is placed through the operating channel of the hysteroscope.

Study Schedule

As noted in Section 2 of this report, the study is classified as over-due because the study could not be started until Conceptus' application for a change in manufacturer under PMA Supplement #P020014/S14 was approved.

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	study initiation	study initiation
August	(b)(4)	
September		
October		
November		
December		
2008		
January		
February		
March		
April		
May		
June		
July		

Revised Timeline

Because Conceptus' application for a change in manufacturer under PMA Supplement #P020014/S14 was approved in August 2007, the initial site enrollment did not occur until late-August, 2007. As a result, the study timeline has been revised and delayed by one month. Table 2(c) below shows the revised timeline of the post-approval study while Table 2(d) shows the revised estimate of patient and investigator enrollment.

Table 2(c): Updated timeline of post approval study

Clinical Study Milestone	Expected Completion Date	Actual Completion Date
Initial Site Enrollment with IRB approval:	August 2007	August 2007
Initial Patient Enrollment:	September 2007	August 2007
86th Site Enrolled with IRB approval (~6 months):	February 2008	TBD
860th Patient Enrolled (~7 months):	September 2008	TBD
Final report prepared:	December 2008	TBD
Final report submitted to FDA:	January 2009	TBD

TBD = To be determined

Table 2(d): Updated Estimate of Investigators and study subjects enrolled by month

Enrollment Milestone Date	Expected # of Investigators enrolled (cumulative)	Expected # of Patients enrolled (cumulative)	Actual #of Investigators enrolled (cumulative)	Actual # of Patients enrolled (cumulative)
2007				
August	study initiation	study initiation	(b)(4)	
September				
October		(b)(4)		
November				
December				
2008				
January			TBD	TBD
February		(b)(4)	TBD	TBD
March			TBD	TBD
April	N/A		TBD	TBD
May	N/A		TBD	TBD
June	N/A	(b)(4)	TBD	TBD
July	N/A		TBD	TBD
August	N/A		TBD	TBD

TBD = To be determined

Summary Data and Interpretation

As of December 12, 2007, (b)(4) case report forms have been submitted to the (b)(4) (b)(4) for cases completed by November 30, 2007. Although investigators have reported enrolling (b)(4) patients, the data has not yet been received by Conceptus through the (b)(4) Therefore, a complete statistical analysis of the data received thus far has not been completed. The unaudited data is summarized below.

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 – November 30, 2007.

Protocol Deviations

(b)(4)