Conceptus

December 12, 2008

FDA CDRH DMC

DEC 15 2008

Received

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: 18-month interim report**
PMA P020014, Report #22
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 18-month interim report on the ESS305 Post-Approval Study.

The information contained in this 18-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
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ESS305 POST-APPROVAL STUDY

18-Month Interim Report

Data current to November 30, 2008

ESS305 POST-APPROVAL STUDY
18-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 12, 2008

Data included in this submission: Clinical Study Data

Type of Submission: Eighteen 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) (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) 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) have agreed to participate in 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. 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	study initiation	study initiation
August	(b)(4)	
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)
2007		
August	study initiation	study initiation
September	(b)(4)	
October		
November		
December		
2008		
January		
February		
March		
April		
May		
June		
July		
August		
September		
October		
November		
December		
2009		
January		
February		
March		
April		
May		
June		
July		
August		
September		
October		

* Physician Enrollment Complete

** Patient Enrollment Complete

Study Schedule

As noted in Section 2 of this report, the study is classified as over-due.

The study is slightly delayed in regards to investigator enrollment. (b)(4) experienced physicians have been officially enrolled; (b)(4) newly trained physicians have been officially enrolled. Investigators are not considered officially enrolled in the study until they complete all required application materials and receive IRB approval. Although (b)(4) physicians in each of the experienced and newly trained groups have agreed to participate, (b)(4) physicians in the newly trained group must still receive IRB approval. (b)(4) investigators originally enrolled in the study were unable to continue participation.

Patient enrollment is also slightly delayed. (b)(4) case report forms have been submitted to Conceptus via the (b)(4). However, investigators have informally reported completing (b)(4) procedures; it is likely that there are additional cases that have been completed but not yet reported or entered. Additionally, this does not include the patients later excluded due to enrollment prior to IRB approval. See Protocol Deviation section for more information.

Table 4: Investigator & Patient Enrollment

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

Summary Data and Interpretation

As of December 11, 2008, (b)(4) case report forms have been submitted to the (b)(4) (b)(4) for cases completed by November 30, 2008. Although investigators have informally 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 through November 30, 2008.

Adverse Events

Three adverse events have been reported during the period from study initiation through November 30, 2008. One 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. The second patient experienced an inconsequential uterine perforation prior to hysteroscope insertion, during dilation of her cervix with a dilator. Hysteroscopy resulted in a uterine perforation before reaching the uterine cavity on the third patient. A vasovagal reaction was previously reported for Patient (b)(6) However, the patient was enrolled prior to the site receiving IRB approval. See Protocol Deviation section for more information.

Patient Number	Adverse Event	Classification	Severity
(b)(6)	vaginal bleeding	Not related to device	Mild
	uterine perforation	Not related to device	Mild
	uterine perforation	Not related to device	Moderate

Protocol Deviations

Deviations to the study protocol included:

- Minor deviations regarding performing the Essure Procedure in a different manner than prescribed in the IFU (b)(4) (b)(4)

(b)(4) . Conceptus plans to include such patients in the data analysis.

There were (b)(4) deviations reported for procedures performed in a different manner than prescribed by the IFU. Some of these deviations may decrease the success of

(b)(4)

A single procedure may have more than one deviation associated with it. Further detail on the number of deviations per site follows.

Site	Patient Numbers*	Number of deviations
#1	(b)(4), (b)(6)	
#2		
#3		
#6		
#7		
#*		
#9		
#10		
#11		
#12		
#13		
#14		
#15		
#16		
#18		
#19		
#20		
#23		
#24		
#25		
#26		
#27		
#28		
#29		
#30		
#31		
#32		
#33		
#35		

Site	Patient Numbers*	Number of deviations
#38	(b)(4), (b)(6)	
#39		
#40		
#41		
#43		
#46		
#50		
#54		
#56		
#57		
#58		
#61		
(b)(4), (b)(6)		
#64		
#67		
#73		
#75		
#80		
(b)(4), (b)(6)		
#84		
#93		

* A single patient may have more than one deviation associated with her procedure.

- (b)(4)