

Conceptus.

December 11, 2012

FDA CDRH DMC
DEC 14 2012
Received

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

RE: **ESSURE-NOVASURE Post-Approval Study**
ESS-NSPAS: 6-month interim report
PMA P020014
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 Essure-NovaSure Post-Approval Study.

The information contained in this 6-month interim report on the Essure-NovaSure 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
Director of Regulatory and Clinical Affairs

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

17

**Post-Approval Study Status Report
6-Month Interim Report**

A Study to Evaluate the Effectiveness of Essure Post-NovaSure
Radiofrequency Endometrial Ablation Procedure Following a
Successful Essure Confirmation Test
Essure-NovaSure PAS
Study# ESS-NSPAS

Date of Report December 11, 2012

Data Current to November 30, 2012

Data current to November 30, 2012

ESS-NSPAS - 6-month Interim Report

1. GENERAL INFORMATION	3
1.1 Sponsor Information.....	3
1.2 Product Information.....	3
2. SUBMISSION INFORMATION.....	4
3. STUDY INFORMATION.....	5
3.1 Study Purpose.....	5
3.1.1 Goals.....	5
3.1.2 Objectives.....	5
3.1.3 Post-Approval Study Endpoints	5
3.2 Subject Population	5
3.2.1 Subject Follow-up Schedule.....	5
3.3 Report Dates	5
3.4 Summary of Study Progress	5
3.4.1 Approval Dates.....	5
3.4.2 Site Enrollment.....	6
3.4.3 Subject Enrollment.....	6
3.4.4 Study Targets: Percentage of subjects reaching each designated study visit.....	6
3.4.5 Comparison of Target vs. Actual Enrollment	6
3.5 Rationale for Study Delay	7
3.6 Subject Tree & Subject Accountability	8
3.7 Summary of Safety and Effectiveness Data	9
3.7.1 Effectiveness Data	9
3.7.2 Adverse Event Data	9
3.7.3 Protocol Deviations	9

1. GENERAL INFORMATION

1.1 Sponsor Information

Name: Conceptus, Inc.
Address: 331 E. Evelyn Avenue
Mountain View, CA 94041 USA

Establishment Registration Number: 2951250

Contact Person: Rachelle Acuña-Narvaez, Director of Regulatory and Clinical Affairs
Telephone: 650-962-4078
Fax: 650-962-5194
Email address: rachelle_acuna-narvaez@conceptus.com

1.2 Product Information

Product Name: Essure Permanent Birth Control System
Model Number: ESS305
Application Number: P020014 - S017

Date of Post-Approval Study Protocol and Supplement Approval: 02/24/2012

2. SUBMISSION INFORMATION

Date of Submission: November 2012

Data Included in this submission: Clinical Study Data

Type of Submission: *Six Month Interim Status Report for Post-Approval Study to Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test*

Additional Information: Supplement to change previously approved Post-Approval Study Protocol was submitted to FDA as P020014/S039, received by CDRH Document Control Center 11/26/2012.

3. STUDY INFORMATION

3.1 Study Purpose

3.1.1 Goals

This Post-Approval Study is a prospective, multi-center, single-arm observational study to monitor and evaluate the effectiveness and safety of Essure when NovaSure is performed following a successful Essure Confirmation Test.

3.1.2 Objectives

- Evaluate the contraceptive failure rate of Essure when NovaSure is performed following a successful Essure Confirmation Test, and
- Monitor the incidence of adverse events and/or complications associated with the performance of NovaSure in the presence of Essure inserts.

3.1.3 Post-Approval Study Endpoints

- Occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure micro-inserts for permanent birth control when NovaSure is performed following a successful Essure Confirmation Test
- Adverse event data

3.2 Subject Population

Post-Approval Study subjects who have been identified as candidates for NovaSure EA and have been/will be relying on Essure micro-inserts for permanent contraception (following a successful Essure Confirmation Test) will be considered. A minimum of (b)(4) female subjects seeking treatment for menorrhagia (i.e. NovaSure), whether wearing or not currently wearing Essure micro-inserts for permanent birth control, and satisfying the eligibility requirements will be enrolled in the Post-Approval Study.

3.2.1 Subject Follow-up Schedule

Subjects will be followed for a total of three years post-NovaSure Endometrial Ablation with evaluations to occur at the 1 week, 12 month, 24 month and 36 month follow-up time points.

3.3 Report Dates

The period covered by this report is June 2012 through November 2012.

The date of database closure for this report is November 30, 2012.

3.4 Summary of Study Progress

3.4.1 Approval Dates

- The date of Essure-NovaSure Post-Approval Study approval was February 24, 2012.

- Conceptus central IRB Study Sponsor Approval was obtained May 1, 2012. Approval for study Site 01 was obtained October 23, 2012.

3.4.2 Site Enrollment

Number of Sites Enrolled	Number of Sites with IRB Approval	Number of Sites Initiated	Estimated Completion Date for Site Enrollment
1	1	1	April 2013

3.4.3 Subject Enrollment

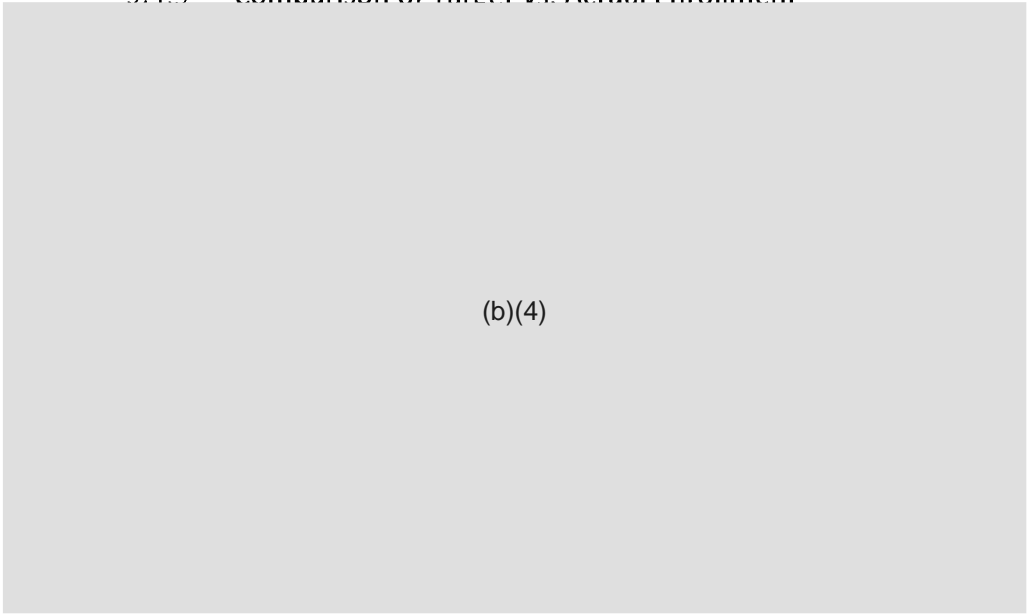
Subject Accrual Start Date: October 24, 2012

Subject Accrual Completion Date: To be determined

3.4.4 Study Targets: Percentage of subjects reaching each designated study visit

Essure Placement	3-Month Confirmation Test	NovaSure EA Procedure	One Week Post-EA Office Visit	One Year Post-EA Phone Call	Two Years Post-EA Phone Call	Three Years Post-EA Phone Call
(b)(4)						

3.4.5 Comparison of Target vs. Actual Enrollment



The actual enrollment is behind the projected enrollment due to a postponed study start as discussed in the following section.

Anticipated Study Completion Date: April 2017

3.5 Rationale for Study Delay

(b)(4)

In order to communicate the delay and additional protocol changes to FDA, Conceptus submitted P020014-S039. In the supplement, Conceptus has requested approval to amend

- Post-Approval Study Milestones to show our current timelines
- Enrollment criteria and the schedule of procedures to streamline the study
- Minor administrative clarification changes.

The original and revised study milestones are included below.

Original Study Milestones

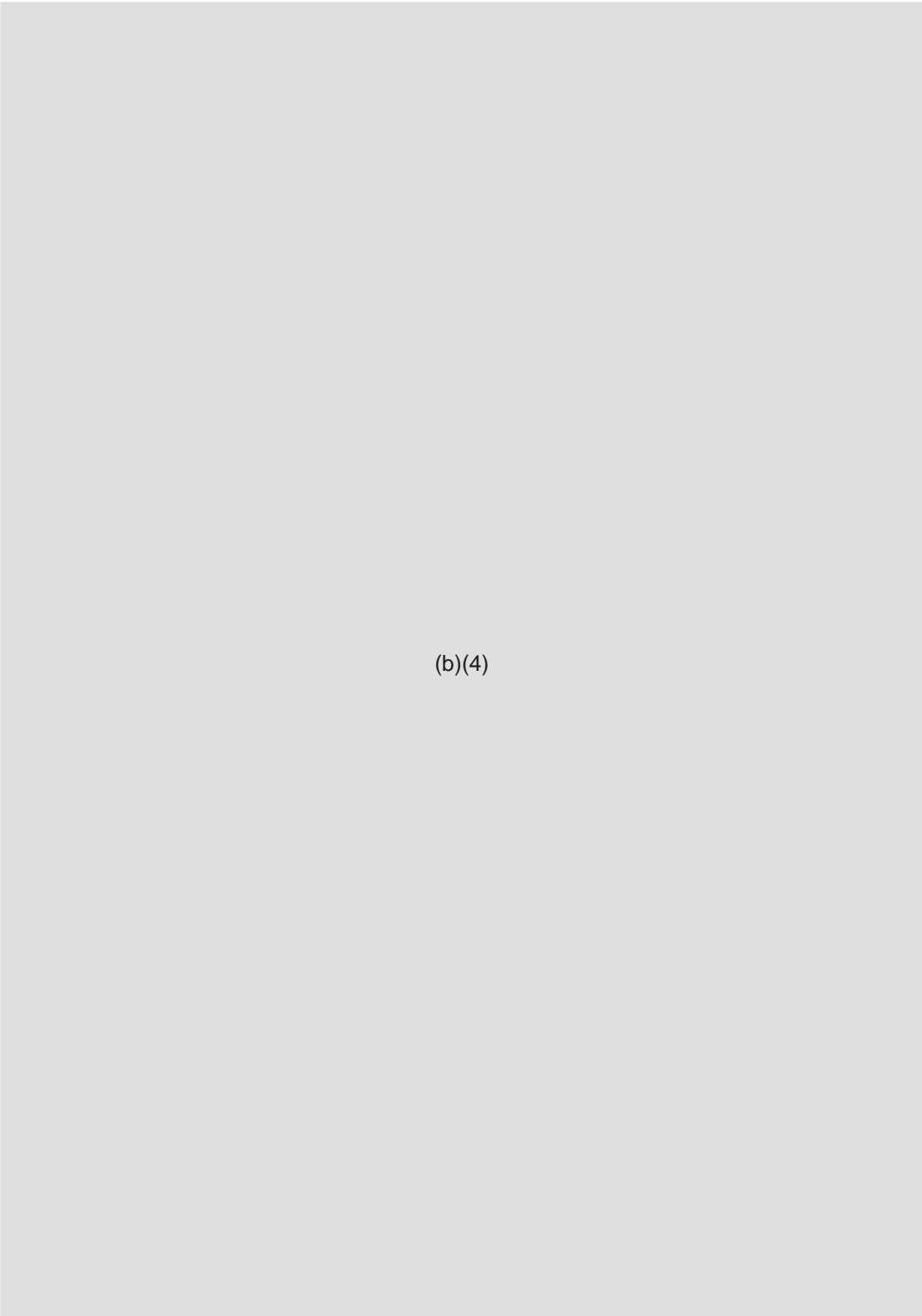
Expected date of study initiation		(b)(4)
Expected rate per month of PAS sites with IRB approval		
Expected date of initiation of subject enrollment		
Expected rate per month per site of subjects enrolled		
Expected date for subject enrollment completion		
Expected date of final subject follow-up		
Expected date complete final PAS report		

Revised Study Milestones (Submitted in Supplement 039)

Expected date of study initiation		(b)(4)
Expected rate per month of PAS sites with IRB approval		
Expected date of initiation of subject enrollment		
Expected rate per month per site of subjects enrolled		
Expected date for subject enrollment completion		
Expected date of final subject follow-up		
Expected date complete final PAS report		

(b)(4)

3.6 Subject Tree & Subject Accountability



(b)(4)

3.7 Summary of Safety and Effectiveness Data

3.7.1 Effectiveness Data

The effectiveness of the intervention is evaluated by the occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure micro-inserts for permanent birth control when NovaSure is performed following a successful Essure Confirmation Test. At this time, no subjects have reached the 1 or 3 year follow-up time point.

3.7.2 Adverse Event Data

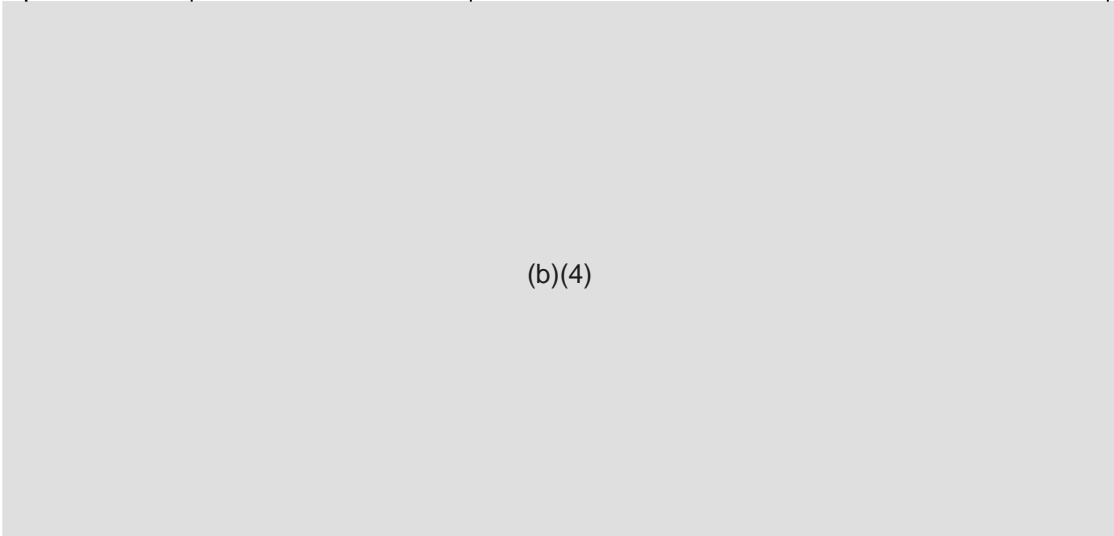
Unanticipated Device Effects: None

Adverse Events: None

3.7.3 Protocol Deviations

There have been no protocol deviations that have affected the evaluation of study results.

Number of Deviations	Deviation	Deviation Explanation
----------------------	-----------	-----------------------



(b)(4)

Post-Approval Study Status Report
6-Month Interim Report

Report Approval Signatures

Document Originator:

(b)(6)

Rachelle Acuna-Narvaez
Director of Regulatory and Clinical Affairs

Rachelle Acuna Narvaez 12/11/12
Signature/Date