Bayer HealthCare LLC
Rachelle Acuna- Narvaez
Bayer Healthcare
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phone: 650-962-4078

September 11, 2013

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: 18 Month report
PMA P020014
Essure System for Permanent Birth Control ESS305

To Whom It May Concern:

In accordance with 21 CFR 822, Conceptus is submitting 1 e-copy of the 18 month interim report on the Essure-NovaSure Post Approval Study.. This electronic copy is being submitted according to FDA's web instructions and it is an exact duplicate of the paper copy.

The information contained in this 18 month report on the Essure-NovaSure Post-Approval Study is considered confidential and Bayer 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 fas at (650) 962-5194, or by email at rachelle.acuna-narvaez@bayer.com.

Sincerely,

Rachelle Acuna - Narvaez

Rachelle Acuna-Narvaez
Director of Regulatory and Clinical Affairs

Post-Approval Study Status Report
18-Month 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: August 24, 2013

Data current to August 7, 2013

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1. GENERAL INFORMATION

1.1 Sponsor Information

Name: Bayer Healthcare
Address: 1011 McCarthy Blvd
Milpitas, California 95035 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@bayer.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: August 24 , 2013

Data Included in this submission: Clinical Study Data

Type of Submission: *18 Month Report for Post-Approval Study to Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test*

3. STUDY INFORMATION

3.1 Study Purpose

3.1.1 Goals

This PAS 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 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 Endometrial Ablation and have been relying on Essure inserts for permanent contraception (following a satisfactory Essure Confirmation Test) will be considered. A minimum of 220 female subjects seeking treatment for menorrhagia (i.e. NovaSure), currently wearing Essure 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 November 2012 through August 07, 2013.
The date of database closure for this report is August 7, 2013.

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.
- Conceptus central IRB Study Sponsor Approval for Version 3.0 of the Study Protocol was obtained January 3, 2013.

3.4.2 Study Milestones

Revised Study Milestones (Approved in Protocol V3, P020014, Supplement 039)

Expected date of study initiation	October 2012
Expected rate per month of PAS sites with IRB approval	2
Expected date of initiation of subject enrollment	November 2012
Expected rate per month per site of subjects enrolled	1
Expected date for subject enrollment completion	March 2014
Expected date of final subject follow-up	April 2017
Expected date complete final PAS report	June 2017

3.4.3 Site Enrollment

Number of Sites Enrolled	Number of Sites with IRB Approval	Number of Sites Initiated	Estimated Completion Date for Site Enrollment
(b)(4)			

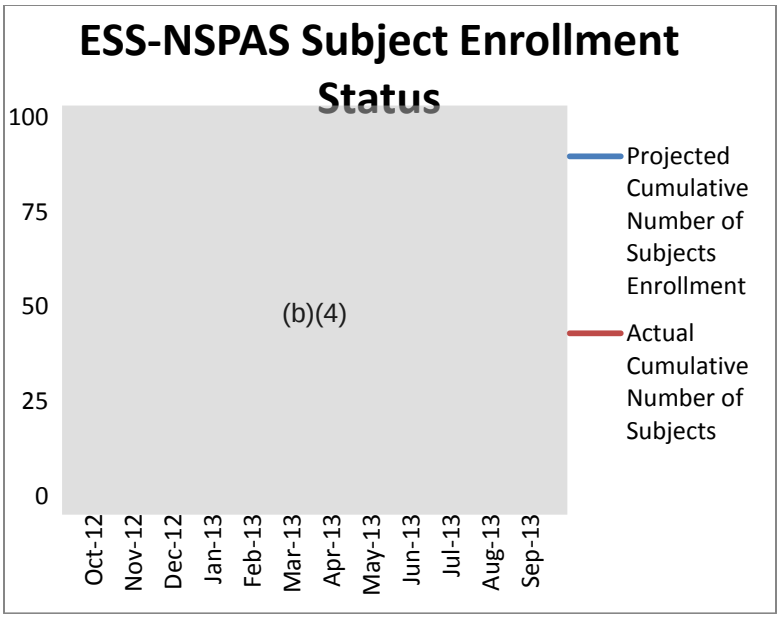
3.4.4 Subject Enrollment

Subject Accrual Start Date: October 24, 2012

Subject Accrual Completion Date: To be determined

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

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)				



The actual enrollment is behind the projected enrollment as discussed in the following section.

Anticipated Study Completion Date: April 2017

3.5 Rationale for Study Delay

Our current site enrollment is (b)(4) sites initiated since February 20, 2013 with (b)(4) additional sites in the process of study qualification. We anticipate these (b)(4) additional sites will complete our site enrollment for the study. There have been several significant factors (listed below) which have delayed subject enrollment. Our current subject enrollment is (b)(4) We have the potential of an additional (b)(4) subjects pending their HSG confirmation tests and anticipate they will enroll in the study in Sep/Oct 2013.

Listed below are a few of the obstacles/challenges that study sites have encountered:

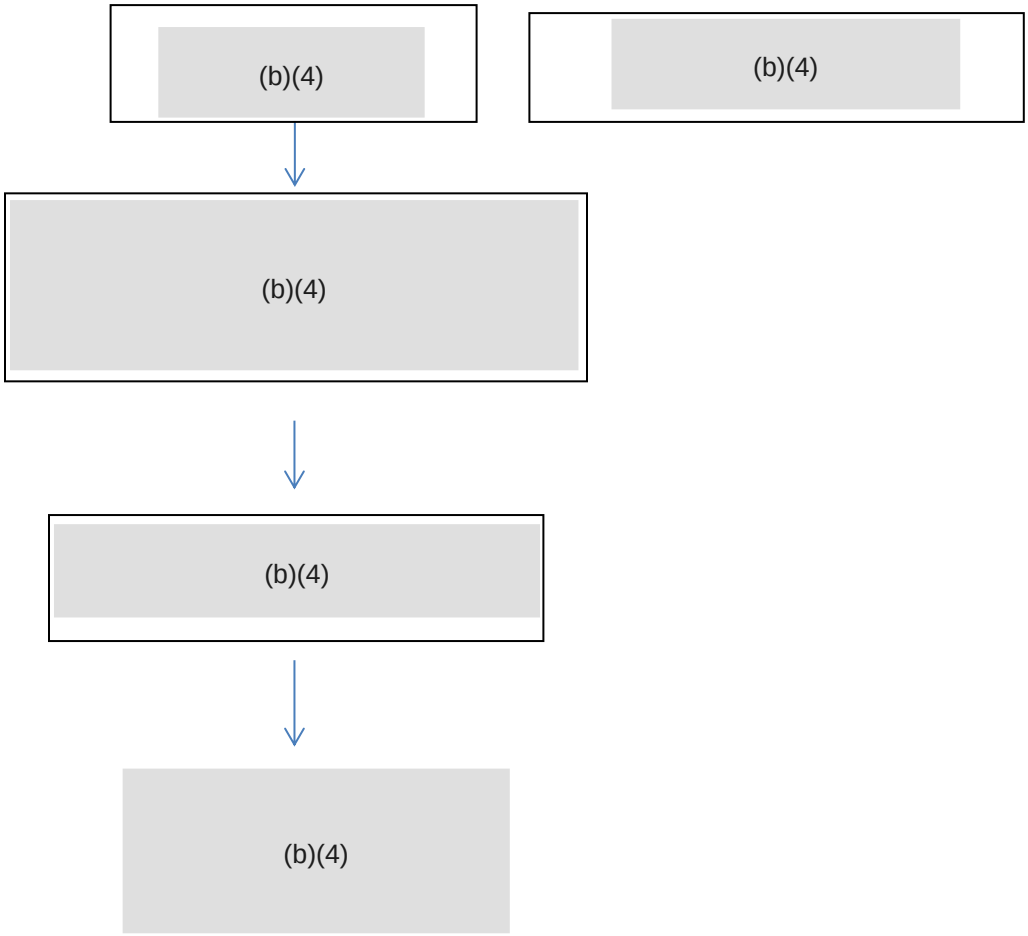
- (b)(4)

In an attempt to increase enrollment some of our strategies in assisting the sites have been as follows:

- (b)(4)

During the first week of (b)(4) we had (b)(4) subjects enroll at (b)(4) of our study sites. We (b)(4)

3.6 Subject Tree & Subject Accountability



3.6 Summary of Safety and Effectiveness Data

3.6.1 Effectiveness Data

The effectiveness of the intervention is evaluated by the occurrence of confirmed pregnancy at 1 year, 2 year and 3 years among subjects relying on Essure inserts for permanent birth control when NovaSure is performed following a successful Essure Confirmation Test. At this time, no subjects have reached the 1, 2 or 3 year follow-up time point.

3.6.2 Adverse Event Data

Unanticipated Device Effects: None

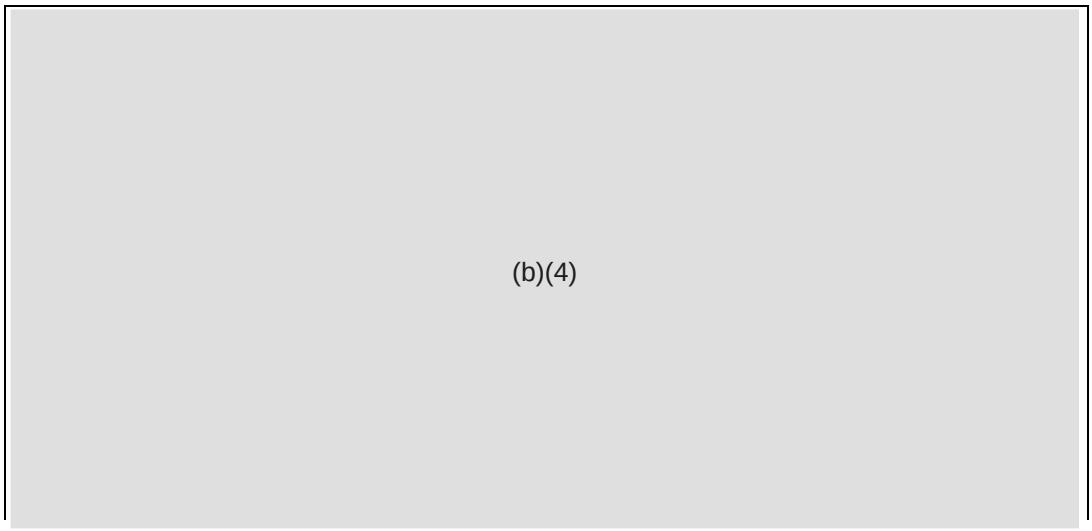
Adverse Events: 3

Subject ID	Event	Date of Onset	End Date	Duration	Severity	Related to micro insert	Outcome
(b)(6)	Cramping	(b)(4)		1 day	Minor	Not related	Recovered w/out treatment
	Dysmenorrhea			1 day	Severe	Not related	Resolved w/out treatment
	Menorrhagia			Intermittent w/ monthly cycles	Moderate	Not related	Subject to schedule repeat ablation in near future.

3.6.3 Protocol Deviations

There have been (b)(4) protocol deviations that have affected the evaluation of study results.

Number of Deviations	Deviation	Deviation Explanation
(b)(4)		


(b)(4)

Bayer HealthCare LLC
Lorie Laird
Bayer Healthcare
Regulatory Affairs Associate
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December 9, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: ESSURE-NOVASURE Post Approval Study
ESS-NSPAS: 18 Month report
PMA P020014/R031/A001
Essure System for Permanent Birth Control ESS305

Dear Dr. Marinac-Dabic:

Bayer Healthcare submits the enclosed response to Report P0209014/R031, the Essure Novasure Post-Approval Study ESS-NSPAS. Questions from FDA are noted in bold italic below, while Bayer response appears in plain text.

1. (b)(4)

Study Milestones as Approved in Protocol V3, P020014, 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)

Revised Study Milestones (b)(4)

Study start date – First patient enrolled	(b)(4)
Expected rate per month per site of subjects enrolled	
Expected rate per year of subjects enrolled	
Expected date for subject enrollment completion	
Expected date of final subject follow-up	
Expected date complete final PAS report	

2. (b)(4)

(b)(4)

Age of Enrolled Study Subjects (b)(4)

(b)(4)

Demographics of Enrolled Study Subjects (b)(4)

Race	
American Indian or Alaska Native	(b)(4)
Asian	
Black or African American	
Native Hawaiian or Other Pacific Islander	
White	
Other	
Ethnicity	
Hispanic	
Not Hispanic	
Gravidity (0-5)	
Parity (0-4)	
BMI (19.1-39.6)	

3. (b)(4)

(b)(4)

Adverse Events Reported at Time of NovaSure Procedure

Subject ID	Event	Date of NovaSure Procedure	Date of AE Onset	End Date	Duration	Severity	Related to micro insert	Outcome
(b)(6)	Cramping	(b)(4)			1 day	Minor	Not related	Recovered without treatment

(b)(4)

None

(b)(4)

None.

Adverse Events Reported at Unscheduled Contacts

Subject ID	Event	Date of NovaSure Procedure	Date of AE Onset	End Date	Duration	Severity	Related to micro insert	Outcome
(b)(6)	Dysmenorrhea	(b)(4)			1 day	Severe	Not related	Resolved w/out treatment
	Menorrhagia				Ongoing	Moderate	Not related	Subject to schedule repeat ablation in near future.

Please find two paper copies and one electronic copy of this response enclosed. The electronic copy is an exact duplicate of the paper copy. The information contained in this PMA report is considered confidential and Bayer Healthcare therefore requests protection of this information in accordance with 18 USC 1905, 21 USC 331(1), 5 USC 552.

Please let me know if you have any questions or need additional information. I can be reached by phone at 650-962-4147 or by fax at 650-691-4729 or by email at lorie.laird@bayer.com..

Sincerely,

Lorie Laird
Regulatory Affairs Associate

P020014/R31/#1

Bayer HealthCare

Bayer HealthCare LLC
Lorie Laird
Bayer Healthcare
Regulatory Affairs Associate
e-mail: Lorie.Laird@bayer.com
phone: 650-962-4147

December 6, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002

Re: P020014/R031
Essure
Study/Requirement Name: Essure Post-NovaSure PAS
Received: September 12, 2013

Dear Dr. Danica Marinac-Dabic:

Please find attached two electronic copies of *Post Approval Study Report Amendment to P020014/R031*. Essure Post-NovaSure PAS.

This eCopy is an exact duplicate of the paper copy attached. The information contained in this PMA Supplement is considered confidential and Bayer therefore requests protection of this information in accordance with 18 USC 1905, 21 USC 331 (l), 5 USC552.

Warm regards,

Lorie Laird
Regulatory Affairs Associate
Bayer HealthCare LLC

p8

Bayer HealthCare

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 19, 2014

Lorie Laird

Bayer HealthCare, LLC
Women's Health
1011 McCarthy Blvd
Milpitas, CA 95035

Tel: +01-650-962-4147
lorie.laird@bayer.com

RE: ESSURE-NOVASURE Post-Approval Study
ESS-NSPAS/16975: 24-month Interim Report
PMA P020014/R032
Essure® System for Permanent Birth Control ESS305

To Whom It May Concern:

In accordance with 21 CFR 822, Bayer HealthCare is submitting three copies of the 24-month interim report on the Essure-NovaSure Post-Approval Study. Two copies are provided as e-copies and are the exact duplicate of the attached paper copy.

The information contained in this 24-month 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) 962-4147, by fax at (650) 691-4729, or by email at lorie.laird@bayer.com.

Sincerely,

Lorie Laird
Regulatory Affairs Associate

Post-Approval Study Status Report
24 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

(Bayer Study #16975)

Date of Report: March 20, 2014

Data current to March 13, 2014

ESS-NSPAS/16975 – 24 Month Interim Report

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1. GENERAL INFORMATION

1.1 Sponsor Information

Name: Bayer HealthCare LLC
Address: 1011 McCarthy Blvd
Milpitas, California 95035 USA

Establishment Registration Number: 2951250

Contact Person: Lorie Laird, Regulatory Affairs Associate
Telephone: 650-962-4147
Fax: 650-691-4729
Email address: lorie.laird@bayer.com

1.2 Product Information

Product Name: Essure Permanent Birth Control System
Model Number: ESS305
Application Number: P020014 - S017
Supplement for Protocol Amendment: P020014 – S039

2. SUBMISSION INFORMATION

Date of Submission: March 20, 2014
Data included in this submission: Clinical Study Data
Date of Post-Approval Study Protocol and Supplement Approval: December 19, 2012

Type of Submission: *24-month Interim 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, Version 3 was submitted to FDA as P020014/S039, received by CDRH Document Control Center November 26, 2012; Approval for Version 3 was received on December 19, 2012.

3. STUDY INFORMATION

3.1 Study Purpose

3.1.1 Goals

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

3.1.2 Objectives

- Evaluate the contraceptive failure rate of Essure when NovaSure is performed following a successful CT, 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 and 3 years after NovaSure EA among subjects relying on Essure inserts for permanent birth control when NovaSure is performed following a successful Confirmation Test.
- Adverse event data.

3.2 Subject Population

The Post-Approval Study target population is subjects who have been identified as candidates for NovaSure Endometrial Ablation and have been relying on Essure inserts for permanent contraception (following a satisfactory CT). The target sample size is 220 women. (Eligibility criteria are provided in the study protocol.)

3.2.1 Subject Follow-up Schedule

Subjects will be followed for a total of three years post-NovaSure EA 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 from November 13, 2012 (date of first subject consent signed) through March 13, 2014.

3.4 Summary of Study Progress

3.4.1 Approval Dates

- Original Essure-NovaSure PAS FDA approval (protocol Version 2) - February 24, 2012.

- Central IRB, Ethical and Independent Review Services (E&I), Study Sponsor Approval (protocol Version 2) - May 1, 2012.
- PAS Supplement FDA approval (protocol Version 3) – December 19, 2012.
- Central IRB (E&I) Study Sponsor Approval (Version 3) (Bayer study #16975) - January 3, 2013.

3.4.2 Study Milestones

Table 1. *Revised Study Milestones*
(approved by FDA in last interactive review – Jan 2014)

Study start date – First subject enrolled (consent signed)	(b)(4)
Expected enrollment rate of subjects per month per site (currently there are 12 sites)	
Expected rate per year of subjects enrolled	
Expected date for subject enrollment completion	
Expected date of final subject follow-up	
Expected date complete final PAS report	

(b)(4)

3.4.3 Site Enrollment

Table 2. ***Current Site Enrollment***

Number of Sites Enrolling Subjects	Number of Sites with IRB Approval	Number of Sites Initiated	Number of Sites Closed*	Number of Sites to be Added
(b)(4)				

*Per investigator's request.

3.4.4 Subject Enrollment:

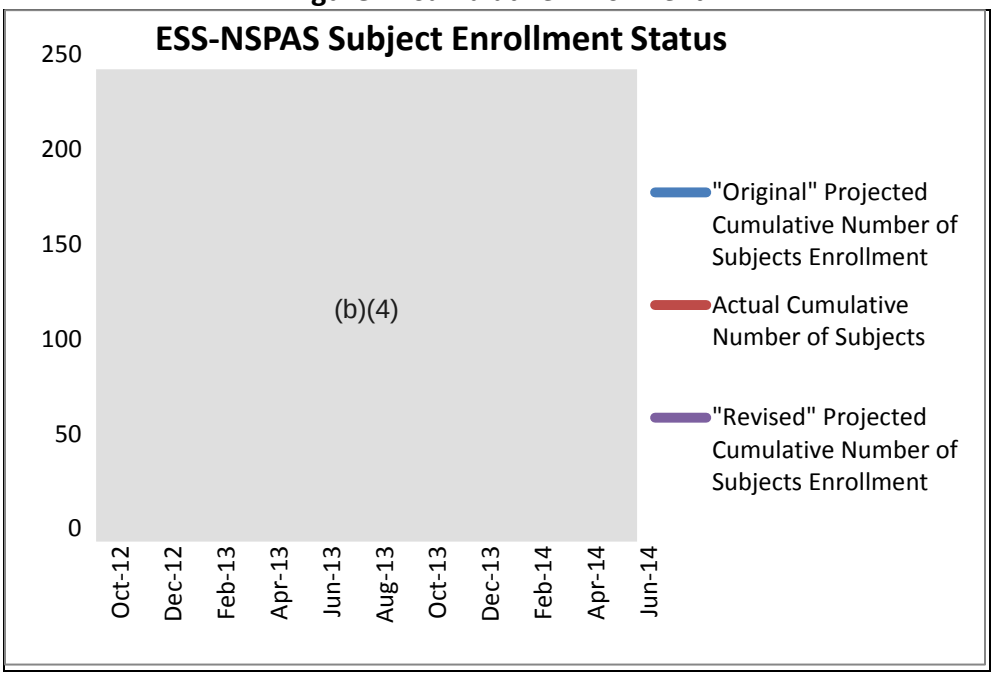
Subject Accrual Start Date (first subject consent signed): *November 13, 2012*
Subject Accrual Completion Date: (b)(4)

3.4.5 Study Targets:

Table 3. *Number of Subjects and Percentage Having Reached Each Designated Study Visit (based on target sample size 220).*

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)				

Figure 1. *Cumulative Enrollment*



The above graph shows the progression of study enrollment. As of the data cut off for this report, study enrollment is on target to meet the revised projected cumulative total that was presented and approved by FDA in the January 2014 interactive review.

3.5 Enrollment Improvement Strategies

As noted in the 18-month report and interactive review in January 2014, the study team is working to ensure that target enrollment is met. Table 4 lists the current strategies to improve enrollment currently in place and their status at the time of this report.

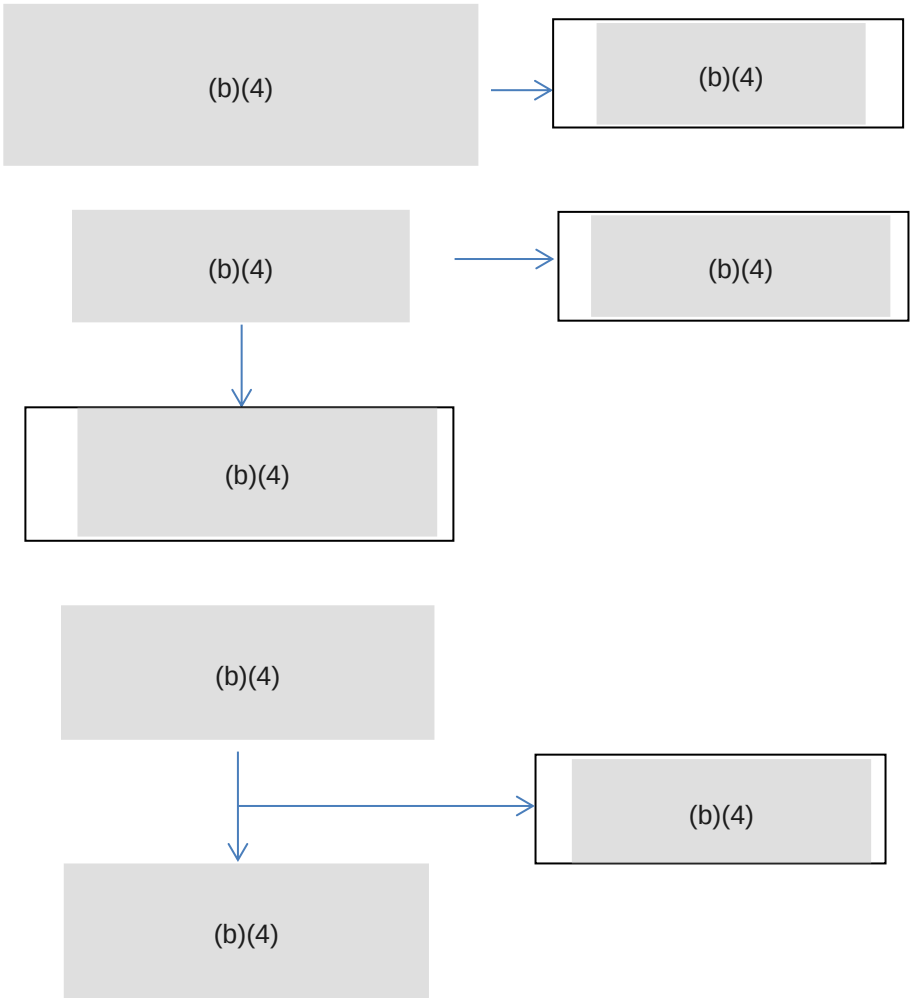
Table 4. *Enrollment Improvement Strategies*

Strategy	Status
(b)(4)	

3.6 Subject Tree & Subject Accountability

(b)(4)

Figure 2. *ESSNS-PAS/16975 Subject Tree*



3.7 Subject Demographics

Demographic characteristics of the (b)(4) nrolled subjects are presented below.

Table 5. *Age of Enrolled Study Subjects* (b)(4)

(b)(4)

Table 6. *Demographics of Enrolled Study Subjects* (b)(4)

Race	**Number**
American Indian or Alaska Native	
Asian	
Black or African American	
Native Hawaiian or Other Pacific Islander	
White	
Other	
Ethnicity	(b)(4)
Hispanic	
Not Hispanic	
Other	
Gravidity (range 0-5)	
Parity (range 0-4)	
BMI (range19-42)	

3.8 Summary of Safety and Effectiveness Data

3.8.1 Effectiveness Data

Occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure inserts for permanent birth control when NovaSure is performed following a successful Essure Confirmation Test. At this time, no pregnancies or expulsions have been reported.

3.8.2 Adverse Event Data

Unanticipated Device Effects: None
Adverse Events: 14

Table 7 summarizes the adverse events that have occurred during the study, the start and stop date, severity, relatedness assessment and outcome. None of the adverse events are serious. Days from Novasure procedure 0 indicates that the AE start date was the same day as the NovaSure EA procedure.

Table 7. *Adverse Events*

aerpt	ID	AE ID	AE Verbatim	Days from Nova-sure to AE	Time Frame	AE Start Date	AE Stop Date	Severity	Relatedness to Es-sure Device	Relatedness to No-vasure Device	Relatedness to No-vasure Proce-dure	Relatedness to Pre-existing Condi-tion	Outcome
1			.		NA			Not checked	Not checked	Not checked	Not checked	Not checked	NA
2			pelvic cramping	0	Day 0			Mild	Not related	Not related	Definitely	Not related	Recovered w/o treatment
3			Pt had nausea following Novasure procedure	0	Day 0			Severe	Not related	Not related	Probably	Not related	Recovered w/ treatment
4			Pt had severe pelvic pain following Novasure procedure	0	Day 0			Severe	Not related	Not related	Probably	Not related	Recovered w/ treatment
5			pelvic pain	1	1-7 days			Moderate	Not related	Unlikely	Possibly	N/A	Recovered w/ treatment
6			pelvic pain	5	1-7 days			Mild	Not related	Not related	Possibly	Unlikely	Recovered w/o treatment
7			Vaginal Itching	8	8-365 days			Mild	Not related	Not related	Possibly	Not related	Recovered w/o treatment
8			fever,pain	10	8-365 days			Mild	Not related	Not related	Probably	Not related	Undetermined
9			infection following ablation	10	8-365 days			Mild	Not related	Not related	Probably	Not related	Recovered w/ treatment
10			longer crampier periods	18	8-365 days			Moderate	Not related	Unlikely	Probably	Not related	Recovered w/ treatment
11			dysmenorrhea	29	8-365 days			Mild	Not related	Not related	Possibly	N/A	Undetermined
12			Tenderness at surgery site from 8/8/13 procedure	77	8-365 days			Mild	Not related	Not related	Not related	Not related	Undetermined
13			Patient had Urinary tract infection	96	8-365 days			Mild	Not related	Not related	Not related	Not related	Recovered w/ treatment
14			postcoital bleeding	145	8-365 days			Mild	Not related	Unlikely	Possibly	Unlikely	Undetermined

(b)(6)

(b)(4)

3.8.3 Protocol Deviations

(b)(4)

P020014 | R32

Bayer HealthCare

FDA CDRH DMC
MAR 24 2014
Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 19, 2014

Lorie Laird

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Women's Health
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lorie.laird@bayer.com

RE: ESSURE-NOVASURE Post-Approval Study
ESS-NSPAS/16975: 24-month Interim Report
PMA P020014/R032
Essure® System for Permanent Birth Control ESS305

To Whom It May Concern:

In accordance with 21 CFR 822, Bayer HealthCare is submitting three copies of the 24-month interim report on the Essure-NovaSure Post-Approval Study. Two copies are provided as e-copies and are the exact duplicate of the attached paper copy.

The information contained in this 24-month 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) 962-4147, by fax at (650) 691-4729, or by email at lorie.laird@bayer.com.

Sincerely,

Lorie Laird
Regulatory Affairs Associate