April 9, 2018

Bayer Pharma AG
Alicia Lowery
Regulatory Affairs Assistant Director
Bayer HealthCare, LLC
921 Parker Street
Berkeley, CA 94710

Re: P020014/S051
Trade/Device Name: Essure System for Permanent Birth Control
Filed: April 6, 2018
Product Code: HHS

Dear Alicia Lowery:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement, which requested approval for a change in the title of the "Patient-Doctor Discussion Checklist" to "Patient-Doctor Discussion Checklist - Acceptance of Risk and Informed Decision Acknowledgement," and for revisions to the patient insert card. Your submission meets the criteria in 21 CFR 814.39(d)(2) for a "Special PMA Supplement - Changes Being Effected." Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device.

In addition, the following restrictions on sale and distribution are required for the safe and effective use of the Essure System for Permanent Birth Control. The sale and distribution by Bayer of the Essure System for Permanent Birth Control are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device prior to its use in the form and manner specified in approved labeling to be provided by Bayer. The sale and distribution by Bayer of the Essure System for Permanent Birth Control are restricted to users and/or user facilities that convey such information to patients in the following manner:

1) The patient brochure "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement", which is part of the approved labeling and will serve as a collective source of information for the patient, is provided to the prospective patient (or the patient's legal representative if applicable) by the implanting physician.

2) The patient brochure "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement" is reviewed by the implanting physician with the patient (or the patient's legal representative if applicable) to assure that the patient understands the risks, benefits, and other information associated with implantation of Essure.

3) The patient (or the patient's legal representative if applicable) is provided an opportunity to sign the designated portions of the patient brochure "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement" to document that the patient has been informed of the risks, benefits, and other information associated with implantation of Essure and has determined to proceed with the implantation of Essure.

4) The designated portions of the patient brochure "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement" are signed by the implanting physician to document that the physician has discussed the benefits and risks of Essure as well as the benefits and risks of available alternatives and has addressed all questions from the patient.

The following must be included in device labeling and any advertising for the Essure System for Permanent Birth Control: "The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer."

FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when

accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

If you have any questions concerning this approval order, please contact Jason Roberts, Ph.D. at (240) 402-6400 or Jason.Roberts@fda.hhs.gov.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health