**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
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Safe Obstetrics Systems, Ltd.
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July 27, 2017

Re: DEN150053
Fetal Pillow
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 884.4350
Regulation Name: Fetal head elevator
Regulatory Classification: Class II
Product Code: PWB
Dated: November 18, 2015
Received: November 20, 2015

Dear Rajiv Varma,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Fetal Pillow, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women requiring a Caesarean Section at full dilation or those requiring a Caesarean Section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use at a gestational age ≥37 weeks.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Fetal Pillow, and substantially equivalent devices of this generic type, into class II under the generic name, fetal head elevator.

FDA identifies this generic type of device as:

> **Fetal head elevator**. A fetal head elevator is a prescription device consisting of a mechanism that elevates the fetal head to facilitate delivery during a Caesarean section.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012.

This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On November 20, 2015, FDA received your De Novo requesting classification of the Fetal Pillow into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Fetal Pillow into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the De Novo request, FDA has determined that the Fetal Pillow indicated for:

> Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women requiring a Caesarean Section at full dilation or those requiring a Caesarean Section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use at a gestational age ≥37 weeks.

can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

| **Identified Risk** | **Mitigation Measures** |
|---|---|
| Adverse tissue reaction | Biocompatibility evaluation |
| Infection | Sterilization validation<br>Shelf life testing<br>Labeling |
| Fetal injury due to device failure | Non-clinical performance testing<br>Shelf life testing<br>Labeling |
| Maternal injury due to device failure | Non-clinical performance testing<br>Shelf life testing<br>Labeling |
| Use error | Labeling |

In combination with the general controls of the FD&C Act, the fetal head elevator is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Performance data must demonstrate the sterility of patient-contacting components of the device.
3. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
4. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    a. Reliability testing of device deployment and retrieval under relevant use conditions must be conducted.
    b. Testing of the maximum force applied to the fetal head in an anatomic model must be conducted.
    c. Testing of uniform application of the elevator mechanism on the fetal head must be conducted.
5. Labeling must include the following:
    a. Contraindication for use in the presence of active genital infection;
    b. Specific instructions regarding the proper placement and use of the device; and
    c. A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact David Birsen at (240) 402-6655.

Sincerely yours,

Randall G. Brockman -S

for Angela C. Krueger
Deputy Director
for Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health