DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 1, 2017

Z-Medica, LLC
Ms. Sheila K. Wallin
Vice President of Clinical and U.S. Regulatory Affairs
4 Fairfield Boulevard
Wallingford, CT 06492 US

Re: DEN160012
D2 Dressing
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 878.4454
Regulatory Classification: Class II
Product Code: POD
Dated: March 16, 2016
Received: March 16, 2016

Dear Ms. Wallin,

This letter corrects our classification order dated June 30, 2017.

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 D2 Dressing, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> D2 Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the D2 Dressing and substantially equivalent devices of this generic type, into class II under the generic name, non-absorbable, hemostatic gauze for temporary internal use.

FDA identifies this generic type of device as:

> **Non-absorbable, hemostatic gauze for temporary internal use.** A non-absorbable, hemostatic gauze for temporary internal use is a prescription device intended to be placed temporarily for control of severely bleeding wounds such as surgical wounds and traumatic injuries. The gauze is coated or impregnated with a hemostatic material which may enhance hemostasis by physical means. The device is intended to be removed once the patient is stabilized.

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 March 16, 2016, FDA received your De Novo requesting classification of the D2 Dressing into class II. The De Novo request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the D2 Dressing into class I or 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 which included biocompatibility, performance bench, and performance animal testing on the D2 Dressing along with clinical data on a previous formulation of the device (D1 Dressing), FDA has determined that the D2 Dressing, indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding as well as control of severely bleeding wounds such as surgical wounds and traumatic injuries, can be classified into class II with the establishment of special controls. FDA believes that 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**
Infection	Shelf Life Testing Sterilization Validation Labeling
Bleeding • Failure of Hemostasis • Recurrence of Bleeding	Animal Performance Testing Technological Specifications
Vascular Obstruction • Ischemia • Emboli Formation	Animal Performance Testing Labeling
Adhesion Formation	Animal Performance Testing Labeling
Adverse Tissue Reaction	Animal Performance Testing Biocompatibility Evaluation
Device Retained in Body Leading to Re-Operation	Animal Performance Testing Non-Clinical Performance Testing Labeling

In combination with the general controls of the FD&C Act, the non-absorbable, hemostatic gauze for temporary internal use is subject to the following special controls:

1. Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Specifically testing must:
    a) Demonstrate that the device is able to achieve hemostasis;
    b) Demonstrate that the device can be radiographically detected; and
    c) Assess pertinent safety endpoints including vascular obstruction and adhesion formation.

2. The device must be demonstrated to be biocompatible.

3. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following tests must be performed:
    a) *In vitro* clot assessment;
    b) Particulate release testing;
    c) Physical characterization, including swelling percent and particulate size;
    d) Chemical characterization;
    e) Radiopacity testing; and
    f) Mechanical integrity testing, including tensile strength and tear strength.

4. Performance data must demonstrate the sterility of the device.

5. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

6. Labeling must include the following:
    a) Instructions for use, including an instruction to remove all visible device components by irrigation;
    b) The maximum amount of time the device may be left within the body;
    c) A shelf life;
    d) A contraindication for intravascular use of the device; and
    e) A warning regarding the potential for adhesion formation.

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 Brendan J. Casey, Ph.D. at 301-796-9607.

Sincerely,

Angela C. Krueger -S

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