



Food and Drug Administration
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October 14, 2014

Vesiflo, Inc.
Kevin M. Connolly
CEO
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Re: DEN130044
inFlow™ Intraurethral Valve-Pump and Activator
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.5140
Regulation Name: Urethral insert with pump for bladder drainage
Regulatory Classification: Class II
Product Code: PIH
Dated: October 25, 2013
Received: October 25, 2013

Dear Kevin M. Connolly,

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 inFlow™ Intraurethral Valve-Pump and Activator, a prescription device under 21 CFR Part 801.109, that is indicated for use in female patients 18 years of age or older who have incomplete bladder emptying due to impaired detrusor contractility of neurologic origin, and who are capable of operating it in accordance with instructions or who have trained caregivers. The device must be replaced every 29 days (or less). FDA concludes that this device should be classified into class II. This order, therefore, classifies the inFlow™ Intraurethral Valve-Pump and Activator, and substantially equivalent devices of this generic type, into class II under the generic name, urethral insert with pump for bladder drainage.

FDA identifies this generic type of device as:

Urethral insert with pump for bladder drainage. A urethral insert with pump for bladder drainage is a catheter-like device with internal pump mechanism that is placed in the urethra. Under patient control the internal pump draws urine out of the bladder when voiding is desired, and blocks urine flow when continence is desired. The device is intended for use by women who cannot empty their bladder due to impaired detrusor contractility.

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 October 25, 2013, FDA received your *de novo* requesting classification of the inFlow™ Intraurethral Valve-Pump and Activator into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the inFlow™ Intraurethral Valve-Pump and Activator 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, FDA has determined that the inFlow™ Intraurethral Valve-Pump and Activator indicated for use in female patients 18 years of age or older who have incomplete bladder emptying due to impaired detrusor contractility of neurologic origin, and who are capable of operating it in accordance with instructions or who have trained caregivers, 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 Measure
Adverse Tissue Reaction	<ul style="list-style-type: none"> • Biocompatibility Testing
Infection	<ul style="list-style-type: none"> • Sterilization Validation • Clinical Testing • Labeling
Reflux or Renal Damage	<ul style="list-style-type: none"> • Non-Clinical (Bench) Testing • Clinical Testing • Labeling
Urethral/Bladder Wall Trauma	<ul style="list-style-type: none"> • Clinical Testing • Labeling
Urinary frequency/urgency	<ul style="list-style-type: none"> • Clinical Testing • Labeling
Device Encrustation	<ul style="list-style-type: none"> • Non-Clinical (Bench) Testing • Labeling
Device Migration	<ul style="list-style-type: none"> • Non-Clinical (Bench) Testing • Clinical Testing
Device Malfunction	<ul style="list-style-type: none"> • Non-Clinical (Bench) Testing • Labeling

Identified Risk	Mitigation Measure
Urine Leakage	<ul style="list-style-type: none"> • Non-Clinical (Bench) Testing • Labeling
Discomfort	<ul style="list-style-type: none"> • Clinical Testing • Labeling

In combination with the general controls of the FD&C Act, the Urethral insert with pump for bladder drainage is subject to the following special controls:

1. The elements of the device that may contact the urinary tract must be demonstrated to be biocompatible.
2. Performance data must demonstrate the sterility of the device components that contact the urinary tract.
3. Performance data must support shelf life by demonstrating continued sterility of the device (or the sterile components), package integrity, and device functionality over the requested shelf life.
4. Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - a. Urine flow rate testing.
 - b. Valve integrity testing.
 - c. Bladder neck retention force testing.
 - d. Pump/valve endurance testing.
 - e. Encrustation testing.
 - f. Remote control reliability, mechanical integrity, and battery life testing.
5. Clinical testing must demonstrate safe and effective use, document the device acceptance rate and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.
6. Labeling must include:
 - a. Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.
 - b. Statement of the maximum insert indwelling period.
 - c. Information on the patient education and support program prior to and during initial device use.
 - d. Information on the patient population for which the device has been demonstrated to be safe and effective.
 - e. Information on how the device operates and the recommended treatment regimen.
 - f. A detailed summary of the device- and procedure-related complications or adverse events pertinent to use of the device.
 - g. An expiration date/shelf life.

7. Patient labeling must be provided and must include:
 - a. Relevant contraindications, warnings, precautions, and adverse events/complications.
 - b. Information on how the device operates and the recommended treatment regimen.
 - c. Information on the patient education and support program prior to and during initial device use.
 - d. Information on the patient population for which there is clinical evidence of safety and effectiveness.
 - e. The potential risks and benefits associated with the use of the device.
 - f. Post-insertion care instructions.
 - g. Alternative treatments.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the urethral insert with pump for bladder drainage they intend to market prior to marketing the device and receive clearance to market from FDA.

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 Mr. John Baxley at (301) 796-6549.

Sincerely yours,

Jonette R. Foy -S

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