**U.S. Food and Drug Administration**
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**FDA News Release**

# FDA permits marketing of urinary prosthesis device for women

## For Immediate Release

October 14, 2014

## Release

The U.S. Food and Drug Administration today allowed marketing of the inFlow Intraurethral Valve-Pump, a replaceable urinary prosthesis for use in female adults who cannot contract the muscles necessary to push urine out of the bladder (impaired detrusor contractility or IDC).

IDC is a condition where patients are unable to spontaneously urinate due to insufficient bladder muscle contraction, which can result from significant neurologic disease or injury such as stroke, multiple sclerosis, spinal cord injury, spina bifida or diabetic neuropathy. IDC is typically managed with various types of catheters, including clean intermittent catheterization (CIC).

“The inFlow device allows women with IDC to urinate, without the need to catheterize daily or be attached to a urine drainage bag,” said William Maisel, M.D., M.P.H., deputy director for science and chief scientist in the FDA’s Center for Devices and Radiological Health. “This may allow for increased mobility and the ability to be more self-sufficient.”

The device has four components: a sterilized, single-use urethral insert component with silicone shaft, fins, and flange; an introducer; an activator; and a sizing component. The device draws urine out to empty the bladder and blocks urine flow when continence is desired. A physician sizes the patient for an inFlow device and performs the initial insertion. After training, device insertion and removal can be performed by the patient or a caregiver. Each inserted component must be replaced at least once every 29 days.

The FDA reviewed data for inFlow through the de novo classification process, a regulatory pathway for some low-to-moderate risk medical devices that are not substantially equivalent to a legally marketed device.

The FDA granted the de novo request based on non-clinical testing and a clinical trial that enrolled 273 women with IDC using CIC. Over half of the women stopped using

the device as a result of discomfort and leakage of urine. The trial showed that 98 percent of the 115 women that continued to use the inFlow device had comparable post-void residual urine volume (measurement of the amount of urine left in the bladder after urination is complete) with those who used the CIC.

Adverse events associated with the device included asymptomatic bacteriuria, urinary tract infection (UTI), bladder inflammation, genital and urinary (genitourinary) pain, blood in the urine (hematuria), urinary leakage (around the device), urinary frequency/urgency, bladder spasms, and vulvar, vaginal, and urethral disorders. It is noteworthy that the most significant of these adverse events – UTI – appears to occur at a lower rate with the inFlow device as compared to CIC. Among patients treated with the inFlow device, UTIs were stable and easily managed with antibiotics.

The inFlow Intraurethral Valve-Pump is manufactured by Vesiflo, Inc., based in Redmond, Washington.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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