DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 9 2000

Mr. Steven Preiss
Vice President
Clinical and Regulatory Affairs
UroSurge, Inc.
2660 Crosspark Road
Coralville, Iowa 52241

Re: K992069
Evaluation of Automatic Class III Designation - UroSurge Percutaneous SANS (Stoller Afferent Nerve Stimulator) Device
Regulatory Class: II
Product Code: 78 NAM
Dated: January 24, 2000
Received: January 27, 2000

Dear Mr. Preiss:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Percutaneous SANS Device that is intended for use in patients suffering from urinary urgency/frequency and urge incontinence. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Percutaneous SANS Device and substantially equivalent devices of this generic type into class II under the generic name, nonimplanted, peripheral nerve stimulator for pelvic floor dysfunction. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as a gastroenterology-urology device under 21 CFR 876.5310, as a nonimplanted, peripheral electrical continence device, which is a device used to provide electrical stimulation to the peripheral nerves associated with pelvic floor function. The device includes the needle electrodes, surface electrode, external pulse generator, and lead wire assembly (which connects all three).

After review of the information submitted in the petition and K992069, FDA has determined that the Percutaneous SANS Device intended for the treatment of patients with urinary urgency/frequency and urge incontinence can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following risks to health associated with this type of device and therapy: (1) discomfort and pain (including throbbing pain) at or near stimulation site including lower leg and foot, (2) bleeding at needle site, (3) redness/inflammation at or near stimulation site, (4) numbness of toes, and (5) stomach ache.

In addition to the general controls of the act, the Percutaneous SANS Device is subject to the following special controls: (1) The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109. (2) Clinical data are necessary. (3) The labeling must include (a) warnings indicating the need to evaluate the patient during treatment for pain or skin irritation/inflammation; (b) precautions indicating the need to read and understand all directions before using this device; (c) specific instructions to describe proper patients set-up prior to the start of treatment, including proper placement of the electrodes; (d) stimulation parameters and duration and frequency of treatments in accordance with the protocol used during clinical trial; and (e) a summary of the clinical data collected including a listing of adverse events reported.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this type of device must submit to FDA a premarket notification submission containing information on the peripheral nerve stimulation device they intend to market prior to marketing the device.

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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this classification order, please contact Ms. Laura J. Byrd at 301-594-2194.

Sincerely yours,

Kimber C. Richter

Kimber Richter, M.D.
Deputy Director, Clinical and Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health