

AUG 3 2000

K994109

PG. 1 OF 4

DETRUSAN 500

Version July 2000

Incontinence Therapy System

Safety and Effectiveness Summary

1. Submitters Name:

Innovamed-USA, Inc.
1140 Lee Blvd. Suite 101
Lehigh Acres
FL 33936

Establishment	
Registration No:	106 43
Owner Operator ID:	903 96 47

2. Name of Device:

Detrusan 500
Device Class II

3. Name of Predicate Devices:

Detrusan 500 Incontinence Therapy System,
K 994109

4. Description of the Device:

I List of Components

Detrusan 500 incontinence Therapy system comes with the external electric stimulator unit and vaginal and anal electrodes (Probes made by "Laborie Medical Technologies")
Vaginal Probes K 990041
Anal Probes K 993721
Approved by FDA.

II Electric Characterization:

Detrusan 500 is a Main net powered electrical stimulator, which provides output stimulus to the probes. The Device can be adjusted to deliver AC voltages in the range up to 30 Volts. The current is depended on the resistor of the patient as standard measuring level at 500 Ohm- 60 mA limited by hardware and software up to 80 mA. Frequencies are adjustable 1 to 100 Hz
The pulse width is adjustable 10 to 400 μ s. 12 preprogrammed follow-ups and frequencies as well as pulse width adjustments are available by calling program number. The Device is constant Voltage stabilized.

Intended Use:

The Detrusan 500 Incontinence Treatment System is indicated for acute, ongoing or chronic treatment of Urge, Stress, or Mixed Urinary Incontinence. The System is indicated to improve urethral sphincter closure, strengthen of the pelvic floor and inhibition of the detruser muscle through reflexive mechanisms.

5. Statement of Indented Use

The Detrusan 500 Incontinence Treatment System is indicated for acute, ongoing or chronic treatment of Urge, Stress, or Mixed Urinary Incontinence. The System is indicated to improve urethral sphincter closure, strengthen of the pelvic floor and inhibition of the detruser muscle through reflexive mechanisms.

6. Statement of technology Characteristics:

A list of comparison shows the difference of the Detrusan 500 and a legally premarket device (k930530/C), - see next Page.

DETRUSAN 500

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Comparison of the Technological Characteristics of the PRS 9300(K930530C) and the Predicate Device Detrusan 500 (K9039647)

Stimulation Characteristics	Proposed device PRS 9300 (K930530/C)	Predicate device Detrusan 500 (K994109)
Intended Use	Treatment of Incontinence	Treatment of Incontinence
Control	Laptop Computer	Preprogrammed CPU
Output (nominal)	0 to 30 VDC ?!	0 to 30 VAC
Waveform:	Square, Symmetrical, Balanced, Biphasic;	Square Symmetrical, Balanced, Biphasic;
Charge Pulse at 500 Ω	60 μ C/phase; net charge/pulse=0	64 μ C/phase; net charge/pulse=0
Frequency	12.5,20,50,100 Hz	1 – 100 Hz
Peak Pulse Intensity	30 VDC ?!	30 VAC
Pulse width	0.3, 1 ms	0.01 – 0.4 ms
Ramps	20%, 40%, 60%, 80%, 100% of "On" time (no down ramp)	1/12 th of the intensity (V)
Duty Cycle	On (sec): 1-80 in 1sec increm. Off (sec): 0-80 in 1 sec increm.	On (sec): 1-60 in1sec.increm. Off (sec):0-60 in 1 sec.increm.
Session Duration (min)	0-30 1 minute increments	0-30 1minute increments
Programmable Features	Not by Patient By Physician: Pulse width, Frequency, Duty Cycle, Session length	Not by Patient! By Physician: Pulse width, Frequency, Duty Cycle, Session length, Programs

<p>Current Density Condition: Full output Settings, 100 Hz, pulse Width at 500 Ω (nominal)</p>	<p>Probe9595 – 0.003 A /cm² Probe9596 – 0.018 A /cm²</p>	<p>Probe 185_5053 0.00403 A / cm² Probe 185_5056 0.01640 A / cm²</p>
<p>Power Density Condition: Full output Settings, 100 Hz, pulse</p>	<p>Probe9595 – 0.047 W/cm² Probe9596 – 0.239 W/cm²</p>	<p>Probe 185_5053 0.12 W / cm² Probe 185_5056 0.12 W / cm²</p>
<p>EMR</p>	<p>Engineering models of PRS9300 have been tested and shown to comply with EN 5501 and IEC 801-3 emissions and immunity, respectively</p>	<p>engineering models of Detrusan have been tested as shown by the EMR Report included first 510K proposal. (K994109)</p>

*
Measurement conditions: of Detrusan:
Range 1: Output Power = 30.V
Range2: Full Output
Settings 100Hz, = max.
Pulse with 400 μ s = max
at 500K Ω



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 3 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ernest H. Czadilek
President
InnovaMed-USA, Inc.
1140 Lee Blvd., Suite 101-103
P.O. Box 1361
Lehigh Acres, FL 33936

Re: K994109
Detrusan 500 Incontinence Therapy System
Dated: May 27, 2000
Received: May 31, 2000
Regulatory Class: II
21 CFR §876.5320/Procode: 78 KPI

Dear Mr. Czadilek:

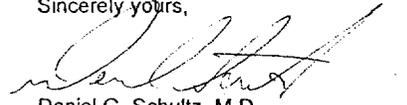
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

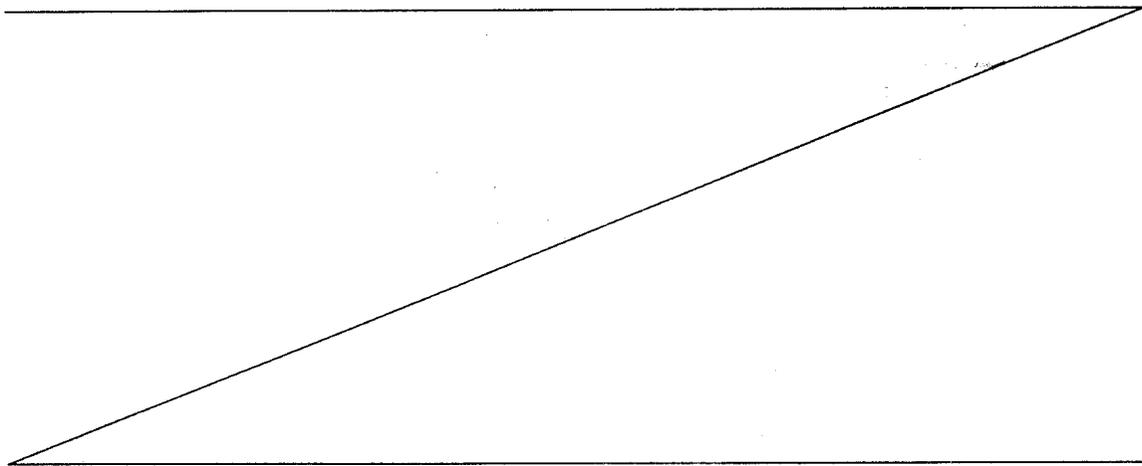
Enclosure(s)

510(k) Number (if known): K 99 41 09

Device Name: DETRUSAN 500
Version May 27, 2000

Indications for Use:

The Detrusan 500 Incontinence Treatment System is indicated for acute, ongoing or chronic treatment of Urge, Stress, or Mixed Urinary Incontinence. The System is indicated to improve urethral sphincter closure, strengthen of the pelvic floor and inhibition of the detrusor muscle through reflexive mechanisms.



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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994109

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use