URODYNAMIX
TECHNOLOGIES LTD

K082701

510(k) Summary
(per 21 CFR 807.92)

DEC 1 8 2008

I. Applicant:

Urodynamix Technologies Ltd
#1485-555 Burrard St.
Box 213
Vancouver, BC
Canada V7X 1M9

Contact Person: André Kindsvater, Director of QA & RA
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Date prepared: September 15, 2008

II. Device Name

Common/Usual Name:	Urodynamics System
Classification Name:	Urodynamics measurement system
Regulation Number:	876.1620
Product Code:	FEN
Classification:	2

III. Predicate Device

The URONIRS 2000 is substantially equivalent to the following predicate device:

- Urodynamic System Tetra Accessory (K073552) from Laborie Medical Technologies Inc.

IV. Intended Use of the Device

The URONIRS 2000 device is intended to be used in conjunction with commercially available uroflowmeters and bladder ultrasound systems for non-invasive testing of bladder activity, aiding in the diagnosis of urinary incontinence and lower urinary tract symptoms. The device is used under the direction of a licensed physician or health care professional.

V. Description of the Device

The URONIRS 2000 is an active medical device indicated for non-invasive testing of bladder activity in an office or hospital setting.

The device consists of a medical grade Tablet PC running the URONIRS application software, a URONIRS base station for data acquisition, a custom designed cable with an optical sensor end and a single use, disposable patch.

The base station provides the laser output and accepts NIRS data input from the sensor via the sensor cable and charges the Tablet PC when plugged in. The base station communicates with the tablet PC via Bluetooth.

During bladder voiding, URONIRS 2000 measures concentration changes in oxygenated haemoglobin (HbO_2), de-oxygenated haemoglobin (Hb) and cytochrome (Cyt) while a commercial uroflowmeter simultaneously measures uroflow data (flow and volume). The data is sent to the tablet PC via Bluetooth connection for display to the clinical users.

Note: The technology and intended use of the URONIRS 2000 is identical to the predicate device Tetra Accessory cleared under K073552

VI. Technical Characteristics

Processing Unit	Medical grade Tablet PC
Mode of Operation	Continuous
Communication	Bluetooth
Uroflow Rate	0 to 50 ml/s
Uroflow Volume	0 to 1000 ml
3 Laser Diodes:	
Wavelengths	785 nm, 808nm and 830nm
Energy Output	Up to 350 mJ
Type of Operation	Pulsed Only, 4 µsec Pulse Width
Class of Laser Products	Class I
Electrical Classification	Class I Equipment Type BF Applied Parts
Degree of Protection Against Ingress of Water	IP20 Equipment

VII. Testing

Verification and Validation was conducted according to written protocols and the test outcomes were documented with test reports including pass/fail determination. Verification was monitored and cross referenced in the Traceability Matrix to ensure all requirements are implemented and verified.

System Validation was undertaken to demonstrate that the URONIRS 2000 device consistently meets the requirements within the intended use and operates as intended under actual operating conditions by accepting the required parameters as input and by returning the expected output, and that the user interface provides a display that is consistent with the data that has been given.

Performance Validation using actual clinical data showed that the URONIRS 2000 has the same performance as the predicate device.

The Safety testing was performed including electrical safety testing, laser safety testing and electromagnetic compatibility testing.

VIII. Safety and Effectiveness

There are no substantial differences between the URONIRS 2000 defined in this 510(k) submission and the stated predicate devices. They are similar to the technologies that are currently used in other similar medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. André Kindsvater, P.E.
Director of QA and RA
Urodynamix Technologies Ltd.
#1485-555 Burrard Street, Box 213
Vancouver, BC, V7X 1M9
CANADA

DEC 1 8 2008

Re: K082701
Trade/Device Name: URONIRS 2000
Regulation Number: 21 CFR 876.1620
Regulation Name: Urodynamics measurement system
Regulatory Class: II
Product Code: FEN and EXQ
Dated: November 26, 2008
Received: November 28, 2008

Dear Mr. Kindsvater:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

URODYNAMIX
TECHNOLOGIES LTD

510(k) Number (if known):

Device Name: URONIRS 2000

Indications for Use:

The URONIRS 2000 device is indicated for non-invasive testing of bladder activity in an office or hospital setting.

Prescription Use _X_ __ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082701