510(k) SUMMARY

Applicant's Name, Address, Phone, Fax, Contact Person, Email, Date Prepared

Limestone Technologies Inc.
Jamie Brown, President
556 O'Connor Drive
Kingston, Ontario K7P 1N3
Canada
Phone: (613) 634-2594
Fax: (613) 634-4098
Email: brownjs@limestonetech.com

APR 26 2006

Date Prepared: September 29, 2005

Device Name, Common/Generic Name and Classification Name

Proprietary Name:	PrefTest Professional Suite™
Common/Usual Name:	Penile Plethysmograph
Classification Name:	Monitor, Penile Tumescence

Predicate Device

Device Name:	MONARCH 21 Penile Plethysmograph (K033126)

Description of the Device

Limestone Technologies Penile Plethysmograph is based on a circumference measurement using a strain gauge transducer which measure penile tumescence in millimeters. PrefTest Professional Suite™ computer software is used to store, tabulate, display and print out the acquired data from a personal computer or lap top.

Intended Use of the Device

The PrefTest Professional Suite™ is used to measure penile tumescence in response to visual and auditory stimuli. Penile tumescence data can later be combined with other standardized psychological testing procedures to assist clinicians with their assessment and treatment of sexual offenders.

Technological Summary between PrefTest Professional Suite and its predicate device

PrefTest Professional Suite™ has the same intended use and function as its' predicate device.

Performance Test Results

Testing for the PrefTest Professional Suite™ software included software validation. A risk analysis performed according to ISO 14971: 2000 was conducted.

Clinical Test Results

Testimonials and published literature supports the safety and effectiveness of this technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 26 2006

Limestone Technologies, Inc.
% Ms. Nancy Ruth
Associate Director, Regulatory Services
CanReg, Inc.
4 Innovation Drive
Dundas, L9H 7P3
CANADA

Re: K052929
Trade/Device Name: PrefTest Professional Suite™
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LIL
Dated: March 31, 2006
Received: April 3, 2006

Dear Ms. Ruth:

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 (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 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052929

Device Name: PrefTest Professional Suite™

Indications For Use: The PrefTest Professional Suite™ is used to measure penile tumescence in response to visual and auditory stimuli. Penile Tumescence data can later be combined with other standardized psychological testing procedures to assist clinicians with their assessment and treatment of sexual offenders.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052929