K053434

MAR 15 2006

Page 1 of 8

Premarket Notification 510(k) Summary
For MyoTrac Infiniti

Date Prepared: 03-07-2006

Applicant: Thought Technology Ltd
2180 Belgrave Avenue
Montreal Quebec
Canada H4A 2L8

Contact: Suresh Sugirtharaja
Design Coordinator
Tel: 489-8251 x127
Fax: 489-8255

Intended Use

Indications for use:

The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.

The MyoTrac Infiniti system is also indicated for the ongoing treatment of the following conditions: Relaxation of Muscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion and Stroke Rehab by Muscle re-education. It is also used for Biofeedback, Relaxation & Muscle Re-Education purposes.

Technical Characteristics Comparison to Predicate Device

This device is compared to Pathways CTS 2000 pelvic floor training system (K023906), InCare PRS Pelvic Floor Therapy System (K974048), Evadri Bladder Control System (K050483), K.E.A.T (K002154) and Detrusan 500 Incontinence Therapy System (K994109). The technical specifications of the MyoTrac Infiniti substantially fall within the range of the Pathways CTS 2000, InCare PRS, Evadri, K.E.A.T and Detrusan 500. Thus the MyoTrac Infiniti system is safe and effective for its intended use and can be considered substantially equivalent to the predicate devices.

	PROPOSED DEVICE MyoTrac Infiniti	Pathway CTS2000 K023906	InCare PRS K974048	K.E.A.T K002154	Evadri Bladder Control System K050483 **(Predicate with AC power source)**	Detrusan 500 (K994109)
Intended Use	Treatment of urinary incontinence EMG Biofeedback	Treatment of urinary incontinence EMG Biofeedback	Treatment of urinary incontinence EMG Biofeedback	Treatment of (stress, urge & mixed) urinary incontinence	Treatment of urinary incontinence EMG Biofeedback	Treatment of urinary incontinence
Primary Functions	Delivery of stimulation and reading of Electromyography	Delivery of stimulation and reading of Electromyography	Delivery of stimulation and reading of Electromyography	Delivery of stimulation	Delivery of stimulation and reading of Electromyography	Delivery of stimulation
Power source	4X AAA 1.5V Alkaline or rechargeable NiMH Battery pack 6VDC – 15W Medical Class II power adapter	Unknown	Unknown	6V Rechargeable lithium- ion battery	Isolated AC to DC power adapter, 115/230VAC switchable input to 6VDC output	Main Powered
Stimulator Output	0 – 100mA	0 -100mA	0-30VDC	0-100mA	0-30Vdc 1% or 5% increment	0-30V
Waveform	Asymmetrical Balanced Pulsed Current	Asymmetrical Balanced Pulsed Current	Square Symmetrical Balanced Biphasic	Balanced Symmetrical Biphasic	Balanced Biphasic, no DC component	Square Symmetrical Balanced Biphasic
Charge/Pulse at 500 ohms	60µC	28µC	60µC	Unknown	Unknown	64µC

K053434
Page 3 of 8

Frequency	12.5, 50,100, 200 Hz	12.5, 50, 100, 200 Hz	12.5, 50, 100, 200 Hz	12.5, 50 Hz	10, 12.5, 20, 50, 100, 200 Hz	1-100Hz
Peak pulse intensity	100mA	100mA	30V	100mA	0-30Vdc 1% or 5% increment	30V
Pulse Width	0.2, ms	0.3ms fixed	0.3, 1 ms	0.3ms fixed	0.3, 1 ms	0.01-0.4ms
Ramps	0 – Duty Cycle on and off ramp.	2 sec on ramp, 1 sec off ramp	On Ramp: 20%, 40%, 60%, 80%, 100% of ON Time, No OFF Ramp	Unknown	Unknown	1/12th of the intensity (V)
Duty Cycle	On (sec): 2 - 20 Off (sec): 2 - 50	On(sec): 1 - 80 Off(sec): 0 - 80	On(sec): 1 - 80 Off(sec): 0 - 80	ON: 5 sec OFF 5sec ON: 5sec OFF: 10sec	ON : 1-80 sec OFF: 0-80 sec	On(sec): 1 - 60 Off(sec): 0 - 60
Session Duration (min)	1-120 minutes	0 – 30	0-30	0-30	1-30min	0-30min
Programmable features	Frequency, Current intensity, pulse width, ramp up and down, session length, by the patient and the physician. Physicians can lock the features for the patient with the exception of the current intensity.	None by Patient: Frequency, Duty cycle, Session Length by physician.	None by Patient: Frequency, Duty cycle, Session Length by physician.	unknown	Unknown	None by Patient: Pulse Width, Frequency, Duty cycle, Session Length by physician.
Vaginal EMG/Stim Probe	Saint-Cloud Probe for vaginal Muscle Stimulation and Biofeedback, manufactured by Saint-Cloud International.	Pathway Vaginal EMG/Stimulation Sensor K993976	InCare Vaginal STIM/EMG probe K891773	Hollister Vaginal STIM Probe K891773	Unknown	Urostym Vaginal STIM/EMG Probe K990041
	Femelex Probe for vaginal Muscle stimulation and Biofeedback manufactured by PhysioMed.					
Vaginal EMG Probe	Thought Technology Ltd Vaginal Probe for	Unknown	Unknown	N/A	Unknown	N/A

K053434
Page 4 of 8

	EMG only K932149B					
Anal EMG/Stimulation Probe	Saint-Cloud Probe for Rectal Muscle Stimulation and Biofeedback, manufactured by Saint-Cloud International.	Pathway Anal EMG/Stimulation Sensor K993976	InCare Anal STIM/EMG Probe K930530	unknown	Unknown	Urostym Anal STIM/EMG Probe K993721
Anal EMG Probe	Thought Technology Ltd Rectal Probe for EMG only K932149B	Unknown	Unknown	N/A	Unknown	N/A
Vaginal EMG/Stim Probe Electrode surface area	St – Cloud 7.4 cm^2 x 2	2.31 cm^2	7.98 cm^2	7.854 cm^2	Unknown	Unknown
	Femelex 10.5 cm^2 x 2					
	Thought Technology 1.53 cm^2					
Anal EMG/Stim Probe Electrode surface area	St – Cloud 2.62 cm^2 & 2.45 cm^2	2.12 cm^2	1.99 cm^2	Unknown	Unknown	Unknown
	Thought Technology 0.91 cm^2					
Current Density (full output)	St – Cloud Vaginal 6.76mA/cm^2	Pathway Vaginal EMG/Stim Sensor: 43m A/cm^2	InCare Vaginal STIM/EMG 3mA/ cm^2	12.73mA/ cm^2	Unknown	4.0mA/cm^2
	Femelex Vaginal 4.76mA/cm^2					
	St – Cloud Rectal 19.72mA/cm^2	Pathway Anal EMG/Stim Sensor: 47m A/cm^2	In Care Anal STIM/EMG 18mA/ cm^2	Unknown	Unknown	16.4mA/cm^2

K053454
Page 548

Power Density (full output @ 500ohms)	St – Cloud Vaginal 22.84mW/cm² Femelex 11.32mW/cm²	Pathway Vaginal EMG/Stim Sensor: 7.79 mW/cm²	InCare Vaginal STIM/EMG 47mW/cm²	81.02 mW/cm²	Unknown	120 mW/cm²
	St – Cloud Rectal 194mW/cm²	Pathway Anal EMG/Stim Sensor: : 8.49 mW/cm²	In Care Anal STIM/EMG 239mW/cm²	Unknown	Unknown	120 mW/cm²
EMG Ranges in µV	0-5, 0-10, 5-10, 0-20, 5-20, 10-20, 0-50, 10-50, 0-100, 50-100, 0-200, 50-200, 100-200, 0-500, 100-500, 0-1000, 0-2000	0 – 5, 0 – 30, 0 - 100, 0 - 1000µV ranges	0-5, 0-10, 0-25, 0-100, 0-250, 0-500 µV ranges	N/A	0-5, 0-10, 0-25, 0-50, 0-100, 0-250, 0-200	N/A
EMG Bandwidth	20 – 500 Hz	20 – 500 Hz	100 -500 Hz	N/A	20-500 Hz	N/A
EMG Signal Processing	Root Mean Square (RMS)	Root Mean Square (RMS)	Root Mean Square (RMS)	N/A	Root Mean Square (RMS)	N/A
EMG Detection	Bipolar	Bipolar	Bipolar	N/A	Bipolar	N/A
Work Period (sec)	2 - 20 seconds	1 – 80 seconds	1 – 80 seconds	N/A	1-80 sec	N/A
Rest Period (sec)	2 - 50 seconds	0 – 80 seconds	0 – 80 seconds	N/A	0-80 sec	N/A
Session Duration (min)	1-120 minutes	1 – 60 minutes	1 – 60 minutes	N/A	1-60 min	N/A
Feedback Modes	Line Graph, Bar Graphs, Digital Display, Signal linked animations	Line Graph, Bar Graphs, Digital Displays, Signal linked Animations	Unknown	N/A	Unknown	N/A

Performance Data:

Non-clinical tests were performed consisted of verification of the product specification, system validation, safety and EMC testing. Device equivalency is determined by a direct comparison of the device functional and hardware specifications of MyoTrac Infiniti system with the legally marketed predicate devices; Pathways CTS 2000 pelvic floor training system (K023906), InCare PRS Pelvic Floor Therapy System (K974048), Evadri Bladder Control System (K050483), K.E.A.T (K002154) and Detrusan 500 Incontinence Therapy System (K994109). Such a comparison table is present in the above section.

Biocompatibility:

The Thought Technology Vaginal EMG Sensor (K932149B), Thought Technology Rectal EMG Sensor (K932149B), St-Cloud Vaginal EMG/Stimulator Electrode, St-Cloud Rectal EMG/Stimulator Electrode, Physiomed Femilex Vaginal EMG/Stimulator Electrode, have been laboratory tested for the safety of the materials and were found to be safe under the standard required for each test.

Conclusion:

The MyoTrac Infiniti system is safe and effective for its intended use. The MyoTrac Infiniti system is substantially equivalent to the predicate devices.

End of 510(k) Summary

K053434
Page 8 of 8

Device Name

Trade Name:	MyoTrac Infiniti System
Common Name:	Non Implanted Electrical Continence Device
Classification Name:	78 KPI, 84HCC ClassII (876.5320, 882.5050 and 890.5850)

Predicate Devices

Trade Name:	Pathway CTS 2000 Pelvic Floor Training System (K023906)
Classification Name:	ClassII, 78 KPI, 84HCC
Trade Name:	InCare PRS Pelvic Floor Therapy System (K974048)
Classification Name:	ClassII, 78 KPI, 84HCC
Trade Name:	K.E.A.T (K002154)
Classification Name:	ClassII, 78 KPI
Trade Name:	Evadri Bladder Control System (K050483)
Classification Name:	ClassII, 78 KPI, 84HCC
Trade Name:	Detrusan 500 Incontinence Therapy System (K994109)
Classification Name:	ClassII, 78 KPI

Description of Device:

The MyoTrac Infiniti device is a non-implanted electrical stimulator for urinary incontinence, it is intended to re-train the urinary continence mechanisms by way of electrical stimulation applied to the pelvic floor musculature and surrounding structures. The device is indicated for treatment of patients with stress incontinence, urge incontinence or mixed incontinence (a combination of stress and urge incontinence). The indications for this use and labeling will be a subset of the overall indications for use. The MyoTrac Infiniti is an electrical muscle stimulator for contraction of muscles as well.

The MyoTrac Infiniti is also an electromyography device. It is intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves and to monitor and display the electrical activity produced by nerves. The indications for use are muscle re-education, relaxation and EMG biofeedback.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Thought Technology, Ltd.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K053434
Trade/Device Name: MyoTrac Infiniti™ System
Regulation Number: 21 CFR §876.5320
Regulation Name: Non-implanted electrical implanted continence device
Product Code: KPI
Regulation Number: 21 CFR §890.5850
Regulation Name: Powered muscle stimulator
Product Code: IPF
Regulation Number: 21 CFR §882.5050
Regulation Name: Biofeedback device
Product Code: HCC
Regulatory Class: II
Dated: February 27, 2006
Received: February 28, 2006

Dear Mr. Mosenkis:

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): K053434

Device Name: MyoTrac Infiniti System

Indications for Use:

The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.

The MyoTrac Infiniti system is also indicated for the ongoing treatment of the following conditions: Relaxation of Muscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion and Stroke Rehab by Muscle re-education. It is also used for Biofeedback, Relaxation & Muscle Re-Education purposes.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053434