January 13, 2021

Thought Technology Ltd.
Zena Butris
Regulatory Affairs Manager
5250 Ferrier, Suite 812
Montreal, Quebec H4P 1L3
Canada

Re: K201014
Trade/Device Name: MyOnyx System
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Codes: KPI, HCC
Dated: December 8, 2020
Received: December 14, 2020

Dear Zena Butris:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews
Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201014

Device Name

MyOnyx System

Indications for Use *(Describe)*

The MyOnyx System is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence, where urinary control may be improved through electrical stimulation that strengthens the pelvic floor muscles or inhibits the detrusor muscle through reflexive mechanisms. The system also uses EMG-based or pressure-based biofeedback to help control and strengthen the pelvic floor muscles in the treatment of urinary incontinence.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (K201014)

January 12, 2021

Device Trade Name:	**MyOnyx System**
Regulation Number:	21 CFR §876.5320
Regulation Name:	Non-implanted electrical continence device
Product Code:	KPI
Regulation Number:	21 CFR §882.5050
Regulation Name:	Biofeedback device
Product Code:	HCC
Regulatory Class:	Class II
Manufacturer:	Thought Technology Ltd.
Establishment Reg. No:	9680487
Address:	5250 Ferrier, Suite 812 Montreal, Quebec H4P 1L3 CANADA Tel: +1 (514) 489-8251 Fax: +1 (514) 489-8255
Regulatory Contact:	Zena Butris, Regulatory Affairs Manager E-mail: zbutris@thoughttechnology.com

This 510(k) Summary has been prepared in accordance with 21 CFR §807.92. It summarizes device safety and effectiveness information to provide an understanding of the basis for a determination of substantial equivalence.

Predicate Device: MyoTrac Infiniti™ System (K053434, Product codes: KPI, IPF, HCC)

Reference Devices

- Pathway CTS2000 Pelvic Floor Training System (K023906, Product Code: KPI)
- Everyway Incontinence Stimulation Electrode (K122194, Product Code: KPI, HIR)

Device Description

This 510(k) submission applies to the MyOnyx System, a re-engineered version of the multifunctional predicate MyoTrac™ Infiniti System (K053434), for use in the treatment of incontinence under medical supervision. The system's architecture, design and functionality are based largely on the currently marketed MyoTrac™ Infiniti System with the notable addition of the companion MyOnyx Mobile App for remote access and a pressure biofeedback modality for use in the treatment of incontinence.

The MyOnyx System includes a palm-sized, multi-functional, 4-channel device with embedded firmware and accessories designed for use under medical supervision to provide:

- electromyographic (EMG) biofeedback;
- pressure biofeedback from pelvic floor muscles;
- electrical stimulation (ES); and
- ES with EMG biofeedback (EMG-triggered stimulation or ETS).

Up to two stimulation programs may run simultaneously. The device can send a gentle, clinician-adjustable electrical current via surface electrodes on purpose-designed probes. The specified off-the-shelf probes are suitable for EMG biofeedback and electrical stimulation. A small electronic pneumatic pump and pressure sensor device is used with a vaginal pressure probe to provide biofeedback from pelvic floor muscles.

The MyOnyx device may be used in one of the following operating modes:

- as a standalone device for electrical stimulation only (autonomous mode); or
- with the MyOnyx Mobile App running on an off-the-shelf tablet for biofeedback, electrical stimulation and EMG-triggered stimulation (remote control mode); or
- with the company's BioGraph® Infiniti software running on a personal computer for biofeedback only (computerized mode).

The device is operated via a graphical interface on an LCD screen and a capacitive touch pad with haptic and audio feedback. The connection to a tablet or personal computer is wireless, via Bluetooth®. Visual, audio and voice feedback and prompts are provided to facilitate device operation on the standalone device, the MyOnyx Mobile App and the BioGraph® Infiniti software.

When used in remote control mode for biofeedback or EMG-triggered stimulation, the device can record on the tablet root-mean-square (RMS) EMG signal and pressure data at 20 samples/s. Stimulation data are not recorded.

When used in computerized mode, up to 4 devices may be connected to a personal computer for physiological data acquisition and biofeedback. In this mode, the device can record on the PC raw EMG and pressure data at 2048 samples/s. For use in this mode with the BioGraph® Infiniti software the device must be configured through a firmware parameter setting ('extended' configuration).

The device is powered by an internal rechargeable Li-ion polymer battery or via a medical grade power supply / battery charger. The internal battery offers up to 8 hours of autonomous device operation.

Intended Use

The MyOnyx System subject to this 510(k) is intended for use in the treatment of incontinence.

Indications for Use

The MyOnyx System is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence, where urinary control may be improved through electrical stimulation that strengthens the pelvic floor muscles or inhibits the detrusor muscle through reflexive mechanisms. The system also uses EMG-based or pressure-based biofeedback to help control and strengthen the pelvic floor muscles in the treatment of urinary incontinence.

The MyOnyx System is a Prescription Use device.

Summary of Non-Clinical / Performance Testing

The re-engineered device was evaluated using a risk management process in accordance with ISO 14971. Verification and validation testing of system specifications, basic safety and essential performance was conducted in conformance with regulatory guidance and current consensus standards for this device type:

Test	Test Method / Standard (FDA Recognition No.)	Acceptance Criteria
Biocompatibility of vaginal pressure probe	ISO 10993-1:2009/COR1:2010 (FR# 2-220)	Cytotoxicity: Noncytotoxic or Mildly cytotoxic (Grades 0-1) per ISO 10993-5; Sensitization: No delayed contact sensitization per ISO 10993-10; Irritation: Non-irritant per ISO 10993-10
Electrical safety	IEC 60601-1 / ES60601-1:2012 (FR# 19-4)	Conformity to applicable basic safety and performance requirements
EMC	IEC 60601-1-2:2014, 4th Ed. (FR# 19-8)	Conformity of device emissions and device immunity to EM disturbances for use in a professional healthcare facility
Basic safety and essential performance of nerve and muscle stimulators	IEC 60601-2-10:2012+A1:2016 (FR# 17-16)	Conformity of electrical stimulation programs to applicable requirements
Basic safety and essential performance of electromyographs and electrical stimulators	IEC 60601-2-40:2016	Conformity of electrical stimulation programs to applicable requirements for accuracy of controls and protection against hazardous stimulation output
Verification of hardware device controls and interfaces	Each device circuit block was verified against hardware design specifications under normal use and, where appropriate, under single fault conditions.	Test results must meet or exceed hardware design specifications
Usability	IEC 60601-1-6:2010+A1:2013 (FR# 5-89) in conjunction with IEC 62366-1:2015 (FR# 5-114)	Conformity of the Usability Engineering Process and related outputs. Acceptance of the modified device by representative end-users operating the device as per accompanying instructions for use.
Software life-cycle processes	IEC 62304:2006+A1:2015 (FR# 13-79)	Firmware development in conformity with requirements for Class B software ('Moderate Level of Concern')
Stimulation firmware unit testing	The Class B (per IEC 62304) stimulation firmware functions and safety features were tested with inputs that verify the effectiveness of error handling and risk control measures	The device responds with expected outputs meeting software design specifications when supplied with predefined test inputs
Firmware and system-level functional verification testing	Device functionality was tested in autonomous mode (stimulation functions) and computerized mode (for biofeedback)	The device responds with expected outputs meeting software design specifications under anticipated use conditions and inputs
MyOnyx Mobile App verification testing	Device functionality was tested in remote control mode	The device responds with expected outputs meeting software design specifications when operated remotely under anticipated use conditions and inputs

Comparison of Technological Characteristics

The appended table shows a side-by-side comparison of key device characteristics between the subject device and the predicate and reference devices that are used to demonstrate substantial equivalence.

Substantial Equivalence Conclusion

The assessment of device differences shows that the MyOnyx System does not raise new or different questions of safety and effectiveness as compared to the predicate devices for use in the treatment of incontinence. Furthermore, the results from the verification and validation activities (non-clinical testing) support a finding of substantial equivalence, as they demonstrate that the subject device fulfills its design and risk management requirements, meets equivalent or more recent consensus standards, and it is therefore as safe and as effective for the intended use as the identified predicate devices.

Side-by-side comparison of key MyOnyx System characteristics with predicate and reference devices that support substantial equivalence (SE)

Device characteristics	Subject device: MyOnyx System	Predicate device: MyoTrac™ Infiniti System (K053434)	Reference devices	Comparison / Brief SE justification
Intended Use	Prescription use device for the treatment of incontinence	Prescription use device for the treatment of incontinence	--	Same
Product Code	KPI, HCC	KPI, HCC (for the proposed intended use)	--	Same
Indications for Use	The MyOnyx System is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence, where urinary control may be improved through electrical stimulation that strengthens the pelvic floor muscles or inhibits the detrusor muscle through reflexive mechanisms. The system also uses EMG-based or pressure-based biofeedback to help control and strengthen the pelvic floor muscles in the treatment of urinary incontinence.	"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."	--	Same
Biofeedback Modalities	• EMG Biofeedback • Pressure Biofeedback	• EMG Biofeedback	**Pathway CTS2000 Pelvic Floor Training System (K023906, Product Code KPI):** Offers EMG and pressure biofeedback with similar technological characteristics for use in the treatment of urinary incontinence	Different The adjunct pressure biofeedback modality does not raise different questions of safety & effectiveness for the intended use in the treatment of urinary incontinence.
EMG Biofeedback Specifications				
EMG Signal Processing	16-bit ADC, Bipolar, 2048 samples/s; ±6250 µV raw signal, 12Hz – 1600Hz (Hardware Filter, Notch filter at 50/60 Hz); 0 – 4420 μV_{RMS}, 20Hz – 500Hz (Band-Pass Filter)	14-bit ADC, Bipolar, 2048 samples/s; ±2828 µV raw signal, 12Hz – 1600Hz (Hardware Filter, Notch filter at 50/60 Hz); 0 – 2000 $\mu V_{RMS,}$ 20Hz – 500Hz (Band-Pass Filter)	--	Different, improved range, resolution, and accuracy.

Device characteristics	Subject device: MyOnyx System	Predicate device: MyoTrac™ Infiniti System (K053434)	Reference devices	Comparison / Brief SE justification
CMMR	> 100 dB	> 100 dB		The differences in biofeedback signal characteristics do not raise different questions of safety & effectiveness for the intended use.
Input Impedance	≥ 10 MΩ	≥ 12 MΩ		
Output EMG Signal	2048 samples/s raw signal or 20 samples/s RMS signal	2048 samples/s raw signal or 20 samples/s RMS signal		
EMG Accuracy	±3%	±5%		
Surface EMG Electrodes	Uni-Gel™ Single Electrodes (Single Use), Thought Technology Ltd, #T3425	Uni-Gel™ Single Electrodes (Single Use), Thought Technology Ltd, #T3425	--	Same
Anal EMG Electrodes	Life-care Anal Probe, Model PR-13A (Single patient, reusable)	Saint-Cloud Anal EMG/Stim Probe; or Thought Technology, Anal EMG Probe (Single patient, reusable)	**Everyway Incontinence Stimulation Electrodes (K122194)** Life-care Anal Probe, Model PR-13A	Different, currently marketed device for the same intended use
Vaginal EMG Electrodes	Life-care Vaginal Probe, Model PR-02A (Single patient, reusable)	Saint-Cloud Vaginal EMG/Stim Probe; or Femelex EMG/Stim Probe; or Thought Technology, Vaginal EMG Probe (Single patient, reusable)	**Everyway Incontinence Stimulation Electrodes (K122194)** Life-care Vaginal Probe, Model PR-02A	Different, currently marketed device for the same intended use
Pressure Biofeedback Specifications				
Pressure Sensor	Electronic pneumatic pump and sensor	Not available	**Pathway CTS2000 Pelvic Floor Training System (K023906)** Reference device with similar technological characteristics and equivalent accessory for use in the treatment of urinary incontinence:	Different The adjunct pressure biofeedback option does not raise different questions of safety & effectiveness for the intended use. The biocompatibility of the vaginal pressure
Size and Weight	10 cm x 7 cm x 2 cm, 90 g			
Enclosure material	Polycarbonate and ABS blend			
Power Source	Powered by the MyOnyx Device			
Power Rating	Max 140mA @ 5Vdc (700mW)			
Pressure range	0 – 200 mmHg			

Device characteristics	Subject device: MyOnyx System	Predicate device: MyoTrac™ Infiniti System (K053434)	Reference devices	Comparison / Brief SE justification
Resolution	0.1 mmHg		Pathway Anal Pressure Sensor manufactured by DesChutes Medical, K934552	probe and the basic safety and essential performance of the device have been verified using current consensus standards.
Nominal pressure	55 mmHg (± 10%), auto-set			
Vaginal Pressure Probe	Single-patient use (reusable), pneumatically inflatable vaginal probe with a silicon bulb and communicating tubing for connection to the Pressure Sensor (35 g, 105 mm x 33 mm)			
Electrical Stimulation				
Electrical Stimulation Modalities	• Neuromuscular Electrical Stimulation (NMES) • EMG-Triggered Stimulation (ETS) using NMES specifications for incontinence	• Neuromuscular Electrical Stimulation (NMES) • EMG-Triggered Stimulation (ETS) using NMES specifications for incontinence	--	Same
Stimulation Programs	User configurable NMES / ETS programs	User configurable NMES / ETS programs	--	Same
Neuromuscular Electrical Stimulation (NMES) specifications for Incontinence Treatments				
Delivery	Synchronous or Alternating; Continuous (no rest phase) for EMG-triggered stimulation	Synchronous	--	Different The waveform, frequency and delivery specification differences do not raise different questions of safety & effectiveness for the intended use. Safety features limit max charge per pulse and power density.
Current Output	0 – 100 mA (Regulated)	0 – 100 mA (Regulated)		
Max Current	100 mA ± 20% @500 Ω	100 mA ± 10% @500 Ω		
Waveform	Symmetrical, rectangular, bipolar, biphasic	Asymmetrical balanced pulsed current		
Pulse Width	150 – 400 µs	50 – 400 µs		
Frequency	5 – 80 Hz	2 – 100 Hz		
Max Charge per Pulse @500 Ω	80 µC	80 µC		
Max Power Density @500 Ω	0.11 W/cm^2 (with smallest electrode conductive surface area on Anal Probe)	0.19 W/cm^2 (with smallest electrode conductive surface area on Anal Probe)		

Device characteristics	**Subject device: MyOnyx System**	**Predicate device: MyoTrac™ Infiniti System (K053434)**	**Reference devices**	**Comparison / Brief SE justification**
Preloaded electrical stimulation programs	Stress incontinence: - Pulse width: 200 µs - Frequency: 45 Hz - Repetitions: 80 - Work time: 6 s - Rest time: 10 s Urge incontinence: - Pulse width: 200 µs - Frequency: 15 Hz - Repetitions: 80 - Work time: 6 s - Rest time: 10 s	Stress incontinence: - Pulse width: 200 µs - Frequency: 45 Hz - Repetitions: 80 - Work time: 6 s - Rest time: 10 s Urge incontinence: - Pulse width: 200 µs - Frequency: 10 Hz - Repetitions: 80 - Work time: 5 s - Rest time: 10 s	--	Identical stress incontinence programs Comparable default urge incontinence programs Basic safety and essential performance have been verified with preloaded programs
Preloaded ETS programs	Stress incontinence ETS: - Pulse width: 200 µs - Frequency: 45 Hz - Repetitions: 63 - Work time: 6 s - Rest time: 10 s	Stress incontinence ETS: - Pulse width: 200 µs - Frequency: 45 Hz - Repetitions: 63 - Work time: 6 s - Rest time: 10 s Plus 3 additional preloaded editable programs for stress incontinence, and 2 additional preloaded editable programs for mixed incontinence		One identical stress incontinence ETS program MyOnyx has no preloaded ETS programs for urge or mixed incontinence; the stress incontinence ETS program may serve as template for custom, user-defined programs Basic safety and essential performance have been verified with preloaded programs

Device characteristics	Subject device: MyOnyx System	Predicate device: MyoTrac™ Infiniti System (K053434)	Reference devices	Comparison / Brief SE justification
Stimulation Electrodes/Probes				
Anal Stimulation Probe	Life-care Anal Probe, Model PR-13A (Single patient, reusable)	Saint-Cloud Anal EMG/Stim Probe (Single patient, reusable)	**Everyway Incontinence Stimulation Electrodes (K122194)** Life-care Anal Probe, Model PR-13A	Different, currently marketed device for the same intended use
Vaginal Stimulation Probe	Life-care Vaginal Probe, Model PR-02A (Single patient, reusable)	Saint-Cloud Vaginal EMG/Stim Probe; or Femelex EMG/Stim Probe (Single patient, reusable)	**Everyway Incontinence Stimulation Electrodes (K122194)** Life-care Vaginal Probe, Model PR-02A	Different, currently marketed device for the same intended use
Operating Characteristics				
Operating Modes	• Standalone using proprietary firmware (autonomous mode via 3.5in LCD and capacitive touch pad with haptic feedback device controls); • With the MyOnyx App running on a tablet (remote control mode via Bluetooth®); • With the BioGraph® Infiniti software running on a personal computer (computerized mode via Bluetooth®)	• Standalone using proprietary firmware (autonomous mode via 8in LCD touch screen); • With the BioGraph® Infiniti software running on a personal computer (computerized mode via USB link)	--	Different The performance of the device has been verified and validated with the new firmware, user interface, Mobile App and specified biofeedback software
Input / Output Channels	2 channels for EMG or pressure biofeedback, electrical stimulation, and EMG-Triggered stimulation 2 additional channels for electrical stimulation only	2 channels for EMG biofeedback, electrical stimulation and EMG-Triggered stimulation	--	Different Basic safety and essential performance have been verified to equivalent standards

Device characteristics	Subject device: MyOnyx System	Predicate device: MyoTrac™ Infiniti System (K053434)	Reference devices	Comparison / Brief SE justification
Physical and Electronic Component Characteristics				
Device Size	155mm L x 83mm W x 20.95mm D	102 mm x 152 mm x 51 mm	--	Different The changes to the electronic enclosure and interface of the device do not raise different questions of safety & effectiveness for the intended use. The device meets current medical electrical equipment safety standards.
Weight	272g	330 g		
Enclosure Materials	Polycarbonate and ABS blend; Plexiglass tinted front panel, aluminum ring for structural support	ABS		
Data Display	3.5in diagonal, 72mm x 54mm, 24-bit color, backlit LCD (320 pixels x 240 pixels)	8in diagonal, 75.5 mm x 72.5 mm, gray-scale LED display (160 x 160 pixels)		
Data Storage	Embedded Multi-Media Card (eMMC), 8GB	Compact Flash Card (User-supplied)		
Communication	Bluetooth® v4.1	USB		
Electrical Safety Specifications				
Power Source	Internal Battery (not user replaceable): Rechargeable (3200mAh) Li-ion Polymer battery certified to IEC 62133 – up to 8 hours of autonomous device operation; External 15W, 5V Medical Grade (Class II Double Insulated) Power Supply / Battery Charger	Internal Battery (user replaceable): 4 x AAA 1.5V Alkaline or rechargeable NiMH Battery pack – up to 4 hours of autonomous device operation; External 15W, 6V Medical Grade (Class II Double Insulated) Power Supply / Battery Charger	--	Different, The changes to the power source do not raise different questions of safety & effectiveness. The device meets current medical electrical equipment safety standards.
Electrical Safety & EMC Standards	IEC/ES 60601-1 (Ed. 3.1) IEC 60601-1-6 IEC 60601-2-10 IEC 60601-2-40 IEC 60601-1-2 (4th Ed.)	IEC/ES 60601-1 (Ed. 2) IEC 60601-1-4 IEC 60601-1-2 (Ed. 2)	--	Different, Current recognized consensus standards