INCONTROL MEDICAL
3225 Gateway Road, Ste. 250
Brookfield, WI 53045

FEB 25 2014

7. 510(k) Summary

Submission Date

December 27th, 2013

Submitter Information

Jessica Andreshak
Director of Quality Assurance and Regulatory Affairs
InControl Medical, LLC
3225 Gateway Road, Ste. 250, Brookfield, WI 53045 USA
Phone: (262) 373.0422
Fax: (262) 373.0463
Email: jandreshak@incontrolmedical.com

Device Information

Table 4. Device Information

Type of 510(k):	Traditional 510(k)
Common Name:	Pelvic Floor Muscle Stimulator
Trade Name (proprietary name):	InToneMV
Classification name:	Stimulator, Electrical, Non-Implantable, For Incontinence
Classification Regulation:	21 CFR 876.5320
Class:	Class II
Product Code:	KPI

Legally Marketed Device for Substantial Equivalence

Table 5. Predicate Device Information

510(k)	Name	Product Code	Manufacturer
K110179	InTone	KPI	InControl Medical, LLC 3225 Gateway Road, Ste. 250 Brookfield, WI 53045 USA
K050483	evadri Bladder Control Systems	KPI	HOLLISTER, Inc. 2000 Hollister Dr. Libertyville, IL 60048 USA

INCONTROL MEDICAL
3225 Gateway Road, Ste. 250
Brookfield, WI 53045

Device Summary

The InToneMV device includes three parts: an insertion unit, control unit, and a software application for clinicians. Each of these parts are summarized below:

- The insertion unit includes (1) an inflation bulb, (2) the customizable inflatable probe, and (3) the flexible tubing connecting the inflation bulb and the inflatable probe. The inflatable probe is inserted into the vagina or rectum and manually inflated by the patient to ensure a customized fit. Electrical stimulation is delivered via stainless steel electrodes on the inflatable probe to induce a contraction of the pelvic floor muscles. Biofeedback is monitored via a pressure sensor within the insertion unit which records changes in pressure related to volitional muscle contraction.
- The control unit includes user keys to initiate and control treatment sessions, and a visual biofeedback graph to provide muscle re-training. The control unit is designed to record and store results of the electrical stimulation and biofeedback sessions for clinician review at follow-up visits.
- The software application is utilized by the clinician to program the control unit and display the results of electrical stimulation and biofeedback sessions.

Intended Use

InToneMV is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of male and female urinary and fecal incontinence.

Equivalence Comparison to the Predicate

The intended use, technology, engineering, performance and user interface for InToneMV is substantially equivalent to the predicate devices as summarized in the chart below.

Feature/ Function	InTone (K110179)	evadri Bladder Control Systems (K050483)	InToneMV (New Device)	Comparison	Impact on Safety and Performance
Intended Use An explicit description of all clinical functions performed by the device, **Indications for Use** Explain when the device is to be clinically used and the intended patient population	The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure feedback for the treatment of urinary and fecal (electromyographic biofeedback) incontinence.	InToneMV is intended to be used in males and females for the treatment of urinary and fecal incontinence.	Substantially equivalent	None

INCONTROL MEDICAL
3225 Gateway Road, Ste. 250
Brookfield, WI 53045

Traditional 510(k) Submission

INTONE MV

Feature/ Function	InTone (K110179)	evadri Bladder Control Systems (K050483)	InToneMV (New Device)	Comparison	Impact on Safety and Performance
Primary Function	Delivery of electrical stimulation	Delivery of electrical stimulation EMG Biofeedback	Delivery of electrical stimulation Visual Biofeedback	Substantially equivalent	None
Warnings or Precautions	(see product labeling)	(see product labeling)	(see product labeling)	Substantially equivalent	None
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	User Manual	Substantially equivalent	None
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	Identical	None
Power Source	4/5 AA nickel metal hydride battery	Isolated AC to DC power adapter, 115/230VAC switchable input to 6VDC output	4/5 AA nickel metal hydride battery	Substantially equivalent	None
Method of line current isolation	n/a (battery)	Unknown	n/a (battery)	Substantially equivalent	None
Patient leakage current	n/a (battery)	Unknown	n/a (battery)	Substantially equivalent	None
Number of output modes	1	1	1	Substantially equivalent	None
Number of output channels	1	1	1	Substantially equivalent	None
Regulated current or voltage?	Regulated voltage	Unknown	Regulated voltage	Substantially equivalent	None
Firmware controlled?	Yes	Yes	Yes	Identical	None
Automatic Overload Trip?	Yes	Unknown	N/A	Substantially equivalent	None
Automatic No-Load Trip?	Yes	Unknown	N/A	Substantially equivalent	None
Automatic Shut Off?	Yes	Unknown	Yes	Substantially equivalent	None
Indicator Display • On/Off Status • Low Battery	 Yes Yes	Unknown	 Yes (via display illumination) Yes	Substantially equivalent	None
Waveform, shape	Dual phase, rectangular pulses	Balanced biphasic, no DC component	Dual phase, rectangular pulses	Substantially equivalent	None
Frequency • Mixed • Stress • Urge	50 Hz - -	10, 12.5, 20, 50, 100, 200 HZ	0 – 50 Hz - -	Substantially equivalent	None
Pulse width • Mixed • Stress • Urge	200 µs/phase - -	0.3, 1 ms	200 µs/phase - -	Substantially equivalent	None
Time • On • Off	 20 seconds 10 seconds	 1-80 seconds 0-80 seconds	 0 – 20 seconds 0 – 20 seconds	Substantially equivalent	None
Total Session Time	12 mins	1 – 30 minutes	0-30 minutes	Substantially equivalent	None
Max output voltage (500Ω)	50 Vdc	0-30 Vdc	50 Vdc	Substantially equivalent	None

INCONTROL MEDICAL
3225 Gateway Road, Ste. 250
Brookfield, WI 53045

Feature/ Function	InTone (K110179)	evadri Bladder Control Systems (K050483)	InToneMV (New Device)	Comparison	Impact on Safety and Performance
Max output current (500Ω)	100 mA	100 Vdc	100 mA	Substantially equivalent	None
Maximum phase charge (500Ω)	50 μC	Unknown	50 μC	Substantially equivalent	None
Electrode surface area	10.5 cm^2 x 2	Various	2.5 cm^2 ± 0.5 cm^2 (x 2)	Substantially equivalent	None
Max current density	4.7 mA/ cm^2	Unknown	20 mA/ cm^2	Substantially equivalent	None
Max average power density (500Ω)	2.38 mW/cm^2	Unknown	10 mW/cm^2	Substantially equivalent	None
Biofeedback	Air pressure, 0 – 2 psi	EMG Pressure, 0 – 350 cm H_2O or combination	Manometric Air pressure, 0 – 2 psi	Substantially equivalent	None
Dimensions	8 x 5 x 4 inches (Inflatable Probe, uninflated)	100 x 70 x 130 mm	Control Unit: 4.8" x 2.4" x 1.1" (+/- 1.0") Inflation bulb: 7.7" x 2.3" x 3.9" (+/- 2.0") Inflatable Probe (with handle): 4.8" x 1.0" x 1.5" (+/- 1.5") Tubing: Maximum 41" long	Substantially equivalent	None
Control housing material	ABS plastics	Plastics	ABS plastics	Substantially equivalent	None
Insertion material	Silicone, plastics	Plastics	Silicone, plastics	Substantially equivalent	None
Tubing Material	NA	N/A	Silicone	Substantially equivalent	None
Packaging or Expiration Dating	1 year for insertion unit	N/A	N/A	Substantially equivalent	None
Sterilization	N/A	N/A	N/A	Identical	None
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Unknown	Clinic or Home use, under direction of physician	Substantially equivalent	None
Patient Interaction: Functions Controllable: An explanation of how the device interacts with the patient.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.	Unknown	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.	Substantially equivalent	None
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming can only be changed by clinician	Unknown	None, programming can only be changed by clinician	Substantially equivalent	None
Override	Yes	Unknown	Yes	Substantially equivalent	None
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided.	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Substantially equivalent	None
Software Level of Concern	Moderate	Unknown	Moderate	Substantially equivalent	None

INCONTROL MEDICAL
3225 Gateway Road, Ste. 250
Brookfield, WI 53045

Testing Summary

The testing for InToneMV included performance, software, electrical safety, EMC and biocompatibility. InToneMV successfully passed all testing.

Clinical evaluations for InToneMV have been completed to support the device as safe and effective according to the intended use.

Risk Management Summary

InToneMV has been designed according to InControl Medical's internal procedures with clear traceability between the design inputs, design outputs verification and validation activities.

InToneMV has been evaluated for risks according to InControl Medical's internal procedures based on ISO 14971. The risks associated with InToneMV were reduced to as low as possible and the risk/benefit analysis was acceptable.

Conclusion

InTone is substantially equivalent to the predicate devices. The data collected and documented throughout this submission provides objective evidence that InToneMV performs as well as or better than the predicate devices for the treatment of incontinence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

InControl Medical, LLC
Jessica Andreshak
Director of Quality Assurance and Regulatory Affairs
3225 Gateway Road, Suite 250
Brookfield, WI 53045

Re: K134020
Trade/Device Name: InToneMV
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI, HCC
Dated: January 4, 2014
Received: February 5, 2014

Dear Jessica Andreshak,

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Statement of Indications for Use

510(k) Number (if known): K134020

Device Name

InToneMV

Indications for Use

InToneMV is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of male and female urinary and fecal incontinence.

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)

Herbert P. Lerner -S
2014.02.25 11:14:15 -05'00'