DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 26, 2014

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

Re: K141158
Trade/Device Name: Apex
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: Class II
Product Code: KPI
Dated: October 13, 2014
Received: October 23, 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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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 Fisher
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)

K141158

Device Name

Apex

Indications for Use

Apex is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It applies stimulation to the pelvic floor muscles to improve strength and support.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(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)

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7. 510(k) Summary

Submission Date

May 2nd, 2014

Submitter Information

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Device Information

Table 4. Device Information

Type of 510(k):	Traditional 510(k)
Common Name:	Pelvic Floor Muscle Stimulator
Trade Name (proprietary name):	Apex
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

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Device Summary

Apex is a hand-held, home-use device designed to treat female stress urinary incontinence. The device includes an inflatable probe. The inflatable probe is inserted into the vagina and manually inflated by the end user 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. Muscle stimulation is used to train and strengthen the pelvic floor muscles in a controlled manner. Muscle stimulation is used to improve the ability of muscles to hold a contraction for an extended period of time and is a treatment for urinary incontinence. During a session, stimulation is delivered to specific muscles to encourage their contraction. This contraction strengthens the muscles and also helps the end user recognize which muscles to activate during self-directed contractions. The level of electrical stimulation is easily controlled by the end user using manual, push-button controls.

Intended Use

Apex is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It applies stimulation to the pelvic floor muscles to improve strength and support.

Apex for over-the-counter use was evaluated for safety through a human factors / usability study. The device labeling and packaging (which includes an educational consumer-focused box, detailed instructions for use, laminated quick reference guide and instructional video) allow the end user to accurately self-diagnose and use the product to treat stress urinary incontinence.

Equivalence Comparison to the Predicate

Electrical muscle stimulation is the technological principle for both Apex and the predicate device, InTone (K110179). It is based on the use of the electrical muscle stimulator to strengthen the pelvic floor muscles. The chart below summarizes the shared and unique technological elements between the InTone and Apex devices. The intended use, technology, engineering, performance and user interface for Apex is substantially equivalent to the predicate devices.

Table 6. Substantial Equivalence Comparison Table

Feature/ Function	K110179 InTone (Predicate)	Apex (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.	Apex is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It applies stimulation to the pelvic floor muscles to improve strength and support.	Substantially equivalent	None: Both devices apply electrical stimulation to strengthen the pelvic floor muscles, as supported by literature, see Appendix 13.
Primary Function	Delivery of electrical stimulation	Delivery of electrical stimulation	Identical	None

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Feature/ Function	K110179 InTone (Predicate)	Apex (New Device)	Comparison	Impact on Safety and Performance
Warnings or Precautions	(see product labeling)	(see product labeling)	Substantially equivalent	None: The warnings and precautions were based on the predicate, InTone, but were reworded for Apex to improve end user understanding for over-the-counter use. The warning and precautions were re-defined according to the FDA guidance document and validated through the Human Factors and Usability Testing.
Contraindications Explain when the device is not to be clinically used	• This device is not intended for diagnostic purposes or critical patient monitoring. • The device is not defibrillator proof. • The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance • Do not use if patient has symptoms of an active urinary tract infection • Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms. • Do not use if patient has undiagnosed pain. • Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation • Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings. • Do not use if patient is currently pregnant or attempting to get pregnant. • Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit • Do not use if the patient has irregular menstrual bleeding cycles • Do not use if the patient has a history or symptoms of urinary retention. • Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Do not use if the patient has overflow incontinence caused by evacuation problems. • Do not use if the patient has severe urine retention in the upper urethras. • Do not use if the patient has complete peripheral denervation of the pelvic floor. • Do not use if the patient has an intestinal clamp.	• Do not use if you are pregnant • Do not use if you are attempting to get pregnant • Do not use if you have a cardiac demand pacemaker or implanted defibrillator • Do not use if you have symptoms of active urinary tract infection, vaginal infections, or localized lesions • Do not use if you have a diagnosis of extra-urethral or overflow incontinence • Do not use if you have severe urine retention • Do not use if you have poor sensation in the pelvic region • Do not use if you have cognitive disabilities, i.e.; Alzheimer's disease or dementia • Do not use if you are unable to properly insert the device per instructions • Do not use if you have active pelvic cancer • Do not use if you have an intestinal clamp • You must be 6 weeks post-pelvic surgery or vaginal childbirth to use this device • Do not use this device for diagnostic purposes or critical patient monitoring • This device is not (external) defibrillator-proof	Substantially equivalent	None: The contraindications are based on the predicate, InTone, but were reworded and reordered for Apex to improve end user understanding for over-the-counter use. The ability to understand the contraindications was validated through collaboration with the supervising physician from the Human Factors and Usability Testing.

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Feature/ Function	K110179 InTone (Predicate)	Apex (New Device)	Comparison	Impact on Safety and Performance
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	Substantially equivalent	None: The user manual is based on the predicate, InTone, but was reworded for Apex to improve end user understanding for over-the-counter use. The manual was validated through collaboration with the supervising physician from the Human Factors and Usability Testing.
Environmental Specifications	For indoor use only	For indoor use only	Identical	None
Power Source	4/5 AA nickel metal hydride battery	4 AAA Alkaline battery	Substantially equivalent	None: Both devices are battery powered. Both devices operate at 3.3V (processor) and 5V (waveform generator); however, the Apex device leverages 4 AAA Alkaline batteries for ease of use and acquisition for the end user. Battery insertion was validated through the Human Factors and Usability Testing.
Method of line current isolation	N/A (battery)	N/A (battery)	Identical	None
Patient leakage current	N/A (battery)	N/A (battery)	Identical	None
Number of output modes	1	1	Identical	None
Number of output channels	1	1	Identical	None
Regulated current or voltage?	Regulated voltage	Regulated voltage	Identical	None
Firmware controlled?	Yes	Yes	Identical	None
Automatic Overload Trip?	Yes	No	Substantially equivalent	None: Although there is no overload trip, Apex does not introduce any safety risks because of the circuit design. The maximum level of stimulation is self-limiting and will not cause end user injury if maximum output is applied.
Automatic No-Load Trip?	Yes	No	Substantially equivalent	None: Although there is no no-load trip, Apex does not cause any safety risks because of the circuit design. The maximum level of stimulation is self-limiting and will not cause end user injury if powered with no load.
Automatic Shut Off?	Yes	Yes	Identical	None
Indicator Display • On/Off Status • Low Battery	 Yes Yes	 Yes (via display illumination) No	Substantially equivalent	None: Apex does not have a low battery indicator. This does not introduce a safety risk because the device will power off when the battery power is too low.
Waveform, shape	Monophasic, alternating polarity, square pulse	Monophasic, alternating polarity, square pulse	Identical	None
Frequency • Mixed • Stress • Urge	 13, 50 Hz - -	 - 50 Hz -	Substantially equivalent	None: The 50Hz frequency for Apex addresses stress urinary

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Feature/ Function	K110179 InTone (Predicate)	Apex (New Device)	Comparison	Impact on Safety and Performance
				incontinence as supported by literature, see Appendix 13.
Pulse width	200 µs/phase	200 µs/phase	Identical	None
Time • On • Off	1 second at 50 Hz 2 seconds no stimulation 2 seconds at 13 Hz 2.1 second no stimulation	1 second at 50 Hz 2 seconds no stimulation	Substantially equivalent	None: The time on and time off are identical for the 50Hz treatment algorithm.
Total Session Time	12 minutes	Total session time of 10-15 minutes • 5-10 minutes electrical stimulation • 5 minutes self-directed contraction (recommended)	Substantially equivalent	None: With Apex, small variances in session time are allowed due to end user preferences.
Max output voltage (500Ω)	34.7 V	34.2 V	Substantially equivalent	None: Apex has a slightly lower output voltage than the predicate. A 1% deviation from the predicate is within the variation of circuit component tolerance.
Max output current (500Ω)	69.1 mA	68.2 mA	Substantially equivalent	None: Apex has a slightly lower max output current than the predicate. A 1% deviation from the predicate is within the variation of circuit component tolerance.
Maximum phase charge (500Ω)	13.8 µC	13.6 µC	Substantially equivalent	None: Apex has a slightly lower max phase charge than the predicate. A 1% deviation from the predicate is within the variation of circuit component tolerance.
Electrode surface area	5.88 cm^2	5.88 cm^2	Identical	None
Max current density	11.8 mA/cm^2	11.6 mA/cm^2	Substantially equivalent	None: Apex has a slightly lower max current density than the predicate. Less than 2% deviation from the predicate is within the variation of circuit component tolerance.
Max average power density (500Ω)	4.05 mW/cm^2	3.95 mW/cm^2	Substantially equivalent	None: Apex has a slightly lower max average power density than the predicate. Less than 2% deviation from the predicate is within the variation of circuit component tolerance.
Biofeedback	Air pressure, 0 – 2 psi	None	Feature removed	None: Biofeedback is strictly an enhanced feature for neuromuscular re-education and the omission of this feature does not adversely impact the safety of the device.
Dimensions (Insertion Unit)	Overall Insertion Unit: 12.2”x 2.5”x 4.0”	Overall Insertion Unit: 12.2”x 2.5”x 4.0”	Identical	None
Control housing material	ABS plastics	N/A	Feature Removed	None: Apex does not include a control unit. The control unit is

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Feature/ Function	K110179 InTone (Predicate)	Apex (New Device)	Comparison	Impact on Safety and Performance
				intended to store and review data collected and to set stimulation levels by the clinician. Since Apex is OTC, there is no need for a control unit.
Insertion material	Silicone, plastics	Silicone, plastics	Identical	None
Packaging or Expiration Dating	1 year for insertion unit	NA	Substantially equivalent	None: Expiration dating is not needed based on the stability of the materials chosen.
Sterilization	N/A	N/A	Identical	None
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Home use, Over-the-counter	Substantially equivalent	None: An over-the-counter indication does not impact safety because the stimulation is controlled by the end user per end user response. Additional safety features are built into the design of the device for the maximum frequency and automatic shut-off.
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.	The end user can control the electrical stimulation levels and the duration of the stimulation session.	Substantially equivalent	None: Stimulation is controlled by the end user per individual response. Additional safety features are built into the design of the device for the maximum frequency and automatic shut-off.
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming can only be changed by clinician	Electrical stimulation levels are set by the end user	Substantially equivalent	None: Stimulation is controlled by the end user per individual response. Additional safety features are built into the design of the device for the maximum frequency and automatic shut-off.
Override	Yes	No	Substantially equivalent	None: The predicate, InTone, includes two units (control unit and insertion unit) and has an override feature so that the patient can pause the session on the control unit without powering the unit off. Apex is a single unit device (insertion unit only) and therefore does not have an override option for suspending the stimulation function. Apex is designed to be powered off by the end user to stop stimulation and improve ease of use. Powering off the device resets the stimulation level to 0.
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	Over-the-counter device. No special knowledge or training required; instruction manual provided	Substantially equivalent	None: The Apex device has been designed to be more intuitive for use by the end user without physician oversight. In both cases, no special knowledge or

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Feature/ Function	K110179 InTone (Predicate)	Apex (New Device)	Comparison	Impact on Safety and Performance
				training is required. End user interaction was validated by the Human Factors and Usability Validation.
Software Level of Concern	Moderate	Moderate	Identical	None

Testing Summary

The following performance testing was provided in support of the substantial equivalence. The testing for Apex included software, electrical safety, biocompatibility and clinical. Apex successfully passed all testing.

Software Verification and Validation Testing:
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the end user.

Electrical Safety and Electromagnetic Compatibility Testing:
Electrical safety and EMC testing were conducted on Apex. The device complies with the IEC 60601-1 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

Biocompatibility Testing:
The biocompatibility evaluation for Apex was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The Insertion Unit is considered tissue contacting for a duration of less than 24 hours. The biocompatibility testing completed included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Clinical Testing:
A clinical literature evaluation was conducted to provide evidence of the safety and efficacy of electrical stimulation for the treatment of female stress urinary incontinence. An appraisal of each article was completed as part of the literature evaluation. The appraisal included an assessment of suitability of each article, a device performance assessment and a device safety assessment.

A human factors / usability study was conducted to assess the safety of the Apex device for over-the-counter use. The human factors / usability study objectives were to: 1) determine if a subject can self-identify as having stress urinary incontinence using package labeling 2) self-limit usage if a contraindication is present 3) safely use the Apex device using only the instructions for use (IFU) provided. The results were favorable leveraging the original packaging and IFU; however, InControl Medical collaborated with the supervising physician to make further labeling

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enhancements including an educational consumer-focused box, detailed instructions for use, laminated quick reference guide and instructional video.

Risk Management Summary

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

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

Conclusion

The non-clinical data supports the safety of the device, and the hardware and software verification and validation demonstrates that Apex performs as intended in the specified use conditions. The clinical literature evaluation, as well as the technological comparison to the predicate device, supports the use of electrical stimulation as an effective treatment of stress urinary incontinence in women. Given that Apex is intended for over-the-counter use, whereas the predicate is intended for prescription use, a human factors / usability study was completed to support the safety of the product labeling for self-diagnosis and use. The data included within this submission supports the use of Apex for over-the-counter as safe and effective.