March 15, 2019

InControl Medical, LLC
Jennifer Koch
Director of Quality & Regulatory Affairs
3225 Gateway Road Suite 250
Brookfield, WI 53045

Re: K182022
Trade/Device Name: ApexMV
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: February 5, 2019
Received: February 7, 2019

Dear Jennifer Koch:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -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

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)*
K182022

Device Name
ApexMV

Indications for Use *(Describe)*
ApexMV is a non-implantable muscle stimulator intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of stress, urge, or mixed urinary incontinence and/or fecal incontinence in adult women.

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.

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7. 510(k) Summary

Date Prepared

Friday, March 15th, 2019

Submitter Information

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Device Information

Table 7.1: Device Information

Type of 510(k):	Traditional 510(k)
Common Name:	Pelvic Floor Muscle Stimulator
Trade Name (proprietary name):	ApexMV
Classification name:	Nonimplanted Electrical Continence Device
Classification Regulation:	21 CFR 876.5320
Class:	Class II
Product Code:	KPI

Legally Marketed Device for Substantial Equivalence

Table 7.2: Predicate Device Information

510(k)	Name	Product Code	Owner
K134020	InToneMV	KPI	InControl Medical, LLC 3225 Gateway Road, Ste. 250 Brookfield, WI 53045 USA
K150183	ApexM	KPI	InControl Medical, LLC 3225 Gateway Road, Ste. 250 Brookfield, WI 53045 USA

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Device Summary

The ApexMV device is a non-implantable muscle stimulator intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of stress, urge, or mixed urinary incontinence and/or fecal incontinence in adult women for Over-the-Counter use. The ApexMV device is to be distributed as a kit that contains the following items:

- 1 – ApexMV device
- 1 – 4 pack of AA batteries
- 1 – 2 oz. tube of InControl Medical Electrode Gel**
- 1 – ApexMV IFU/ User Manual
- 1 – ApexMV Quick Reference Card
- 1 – Screw driver
- 1 – Travel Bag
- 1 – Animation Video

**The InControl Medical Electrode Gel is privately labeled for InControl Medical. It is a Pre-Amendment Class II Medical Device under D039725.

The kit contents are substantially equivalent to the ApexM (K150183) and InToneMV (K134020) that are distributed on the market by InControl Medical. The inclusion of the screw driver in the ApexMV kit is for the screw that holds the battery cover panel in place on the back side of the control unit.

The ApexMV device consists of a hand held control unit with bio-feedback and inflation pump attached to a customizable inflatable probe via flexible tubing. The customizable inflatable probe is inserted vaginally or rectally 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 also used to improve the ability of the muscles to hold a contraction for an extended period of time for the treatment of stress, urge, or mixed urinary and/or fecal incontinence in adult women. During a session, high and low frequency stimulation is delivered by the device. The higher frequency stimulation is delivered to specific muscles to encourage their contraction, strengthening the muscles and helping the end user recognize which muscles to activate during self-directed contractions. Lower frequency stimulation calms the detrusor muscle, decreasing symptoms of urgency. The level of electrical stimulation is easily controlled by the end user using manual, push-button controls.

Indications for Use

ApexMV is a non-implantable muscle stimulator intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of stress, urge, or mixed urinary incontinence and/or fecal incontinence in adult women.

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Equivalence Comparison to the Predicate

Electrical muscle stimulation is the technological principle for ApexMV and the predicate devices, ApexM (K150183) and InToneMV (134020). It is based on the use of electrical muscle stimulation to strengthen the pelvic floor muscles and surrounding structures. The chart below summarizes the shared and unique technological elements between ApexMV and the predicate devices, ApexM (K150183) and InToneMV (K134020). The intended use, technology, engineering, and performance for the ApexMV is substantially equivalent to the predicate devices, ApexM (K150183) and InToneMV (134020).

Table 7.3: Substantial Equivalence Comparison Table

Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	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	InToneMV is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of male and female urinary and fecal incontinence	ApexM is a non-implanted muscle stimulator designed to treat, stress, urge, and/or mixed urinary incontinence in women. It applies stimulation to the pelvic floor muscles to improve strength and support.	ApexMV is a non-implantable muscle stimulator intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of stress, urge, or mixed urinary incontinence and/or fecal incontinence in adult women.	Substantially equivalent	None: These devices apply the same electrical stimulation to strengthen the pelvic floor muscles, as supported by literature.
Primary Function	Delivery of electrical stimulation Visual biofeedback	Delivery of electrical stimulation	Delivery of electrical stimulation Visual biofeedback	Identical to InToneMV	None
Warnings or Precautions	(See product labeling)	(See product labeling)	(See product labeling)	Substantially equivalent	None: ApexMV warnings and precautions are identical to ApexM and InToneMV, which were

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
					defined in accordance with the FDA guidance document and validated through the Human Factors Usability Testing.
Contraindications Explain when the device is not to be clinically used	• Patients with a pacemaker or implanted defibrillator require cardiac clearance before electrical stimulation is offered. • Patients with symptoms of active urinary tract infection, vaginal infections, localized lesions, or other undiagnosed symptoms. • Patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Patient has overflow incontinence caused by evacuation problems. • Patient has severe urine retention in the upper urethra or other symptoms of urine retention.	• 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.;	• 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 electrical device • 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	Substantially Equivalent	None

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
	• Patients with neurological deficiency that does not permit proper sensory perception of stimulation or complete denervation of the pelvic floor. • Patients with cognitive disabilities, i.e.; Alzheimer's disease or dementia. • Patients who are currently pregnant or attempting to get pregnant. • Patients with anatomical pelvic structures that do not permit proper and complete placement of the Insertion Unit. • Patients with active pelvic malignancy. • Patients with an intestinal clamp. • Patients should be 6 weeks post-pelvic surgery or vaginal childbirth. • Device should not be used for diagnostic purposes or critical patient monitoring. • Device is not (external) defibrillator-proof.	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	• 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		

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
Labeling Summary Clarity to ensure safer or more effective use	User Manual and Quick Reference Patient Guide Card	User Manual and Quick Reference Patient Guide Card	User Manual and Quick Reference Patient Guide Card	Identical to predicates	None: ApexMV User Manual and Quick Reference Patient Guide Card user were based on the labeling and use for ApexM for Over-The-Counter use and was validated through the Human Factors Usability Testing.
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	Identical to predicates	None
Power Source	4/5 AA nickel metal hydride battery	4-AAA Alkaline battery	4 -AA Alkaline battery	Substantially equivalent	None
Method of line current isolation	N/A (battery)	N/A (battery)	N/A (battery)	Identical to predicates	None
Patient leakage current	N/A (battery)	N/A (battery)	N/A (battery)	Identical to predicates	None
Number of output modes	1	1	1	Identical to predicates	None
Number of output channels	1	1	1	Identical to predicates	None
Regulated current or voltage?	Regulated voltage	Regulated voltage	Regulated voltage	Identical to predicates	None
Firmware controlled?	Yes	Yes	Yes	Identical to predicates	None
Automatic Overload Trip?	No	No	No	Identical to predicates	None

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
Automatic No-Load Trip?	No	No	No	Identical to predicates	None
Automatic Shut Off?	Yes	Yes	Yes	Identical to predicates	None
Indicator Display • On/Off Status • Low Battery	Yes (via display illumination) Yes	Yes (via display illumination) No	Yes Yes (via on screen warning)	Substantially equivalent to InToneMV	None
Waveform, shape	Monophasic, alternating polarity, square pulse	Monophasic, alternating polarity, square pulse	Monophasic, alternating polarity, square pulse	Identical to predicates	None
Waveform Frequency • Urge • Stress • Mixed	13 Hz - Urge Incontinence 50 Hz - Stress Incontinence 13/50 Hz – Mixed	13 Hz - Urge Incontinence 50 Hz - Stress Incontinence 13/50 Hz – Mixed	13 Hz - Urge Incontinence 50 Hz - Stress Incontinence 13/50 Hz – Mixed	Identical to predicates	None
Waveform Pulse width	200 μs/phase	200 μs/phase	200 μs/phase	Identical predicates	None
Waveform Pattern	1 second at 50 Hz 2 seconds no stimulation 2 seconds at 13 Hz 2 second no stimulation	1 second at 50 Hz 2 seconds no stimulation 2 seconds at 13 Hz 2 second no stimulation	1 second at 50 Hz 2 seconds no stimulation 2 seconds at 13 Hz 2 second no stimulation	Identical to predicates	None

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
Total Session Time	Total session time of approximately 12 minutes • 2 minutes of volitional stimulation • 5 minutes of muscles stimulation • 5 minutes of volitional contractions.	Total session time of 10-15 minutes • 5-10 minutes electrical stimulation • 5 minutes self-directed contractions (recommended)	Total session time of approximately 11 minutes • 7 minutes of electrical stimulation • 3.5 minutes of self-directed contractions (recommended)	Substantially equivalent to predicates	None
Max output voltage (500Ω)	40.0 V peak	40.0 V peak	40.0 V peak	Identical to predicates	None
Max output current (500Ω)	80.0 mA peak	80.0 mA peak	80.0 mA peak	Identical to predicates	None
Maximum phase charge (500Ω)	16.0 µC	16.0 µC	16.0 µC	Identical to predicates	None
Electrode surface area	2.5 cm^2 ± 0.1 cm^2 x 2	5.9 cm^2 ± 0.1 cm^2 x 2	3.9 cm^2 ± 0.1 cm^2 x 2	Substantially equivalent to predicates	None
Max current density	32.0 mA/cm^2	13.6 mA/cm^2	20.5 mA/cm^2	Substantially equivalent to predicates	None
Max average power density (500Ω)	12.8 mW/ cm^2	5.4 mW/cm^2	8.2 mW/cm^2 peak	Substantially equivalent to predicates	None
Biofeedback	Manometric Air pressure, .01 – 2 psi	None	Manometric Air pressure, .01 – 2 psi	Substantially equivalent to predicates	None

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
Dimensions (Insertion Unit)	Control Unit: 4.8" x 2.4" x 1.1" (+/- 0.1") Inflation bulb: 7.7" x 2.3" x 3.9" (+/- 0.1") Uninflated Probe: 2.7" x 0.5" x 0.9" (+/- 0.1") Inflated Probe (2.0 PSI): 2.4" x 1.4" x 1.7" (+/- 0.1") Tubing: 40.0" (+/- 1.0") long	Overall Insertion Unit: 11.8"x 2.3"x 3.9" (+/- 0.1") Uninflated Probe: 5.1" x 1.2" x 1.5" (+/- 0.1") Inflated Probe: 5.0" x 1.6" x 2.1" (+/- 0.1")	Control Unit: 6.2"x3.3"x 1.8" (+/- 0.1") Uninflated Probe: 4.1" x 0.5" x 0.8" (+/- 0.1") Inflated Probe: 3.9" x 1.4" x 1.7" (+/- 0.1") Tubing: 40.0" (+/- 1.0") long	Substantially equivalent to InToneMV	None
Control housing material	ABS plastics	N/A	ABS plastics, TPE over molded gaskets and hand grip	Substantially equivalent	A TPE over molded gasket was added to the plastic housing to comply with electrical safety standards for home use devices (H20 ingress).
Insertion probe material	Silicone, stainless steel	Silicone, stainless steel	Silicone, stainless steel	Identical	None
Expiration Dating	N/A	N/A	N/A for the ApexMV insertion unit. 4 year shelf life for the electrode gel	Identical	The electrode gel supplied in the kits for InToneMV, ApexM and ApexMV has a 4 year shelf life that was not stated in the original submissions.
Overall Device Weight	~ 0.8lbs.	~ 0.8 lbs.	~ 0.8 lbs.	Identical	None

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
Packaging (Overall Weight)	~ 2.6 lbs.	~ 2.0 lbs.	~ 2.2 lbs.	Substantially equivalent	The InToneMV, ApexM and the ApexMV are all packaged with the same customized foam that surrounds the device, and same corrugated cardboard exterior box for the Patient Unit.
Sterilization	N/A	N/A	N/A	Identical to predicates	None
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of a Physician or health care provider.	Home use, Over-the-counter	Home use, Over-the-counter	Identical to ApexM	None
Operating Conditions:	Temperature: 32 - 130°F (O-54°C) Relative Humidity: 15-95%, non-condensing	Temperature: 32 - 130°F (O-54°C) Relative Humidity: 15-95%, non-condensing	Temperature: 41 - 104 °F (5-40°C) Relative Humidity: 15-95%, non-condensing	Substantially equivalent to predicates	None
Storage and Transportation Conditions:	Temperature: -4-150°F (-20 -65°C) Relative Humidity: 10-95%, non-condensing	Temperature: -4-150°F (-20 -65°C) Relative Humidity: 10-95%, non-condensing	Temperature: -13 - 158°F (-25 -70°C) Relative Humidity: 10-95%, non-condensing	Substantially equivalent to predicates	None

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Feature/ Function	K134020 InToneMV (Predicate) manufactured by InControl Medical, LLC.	K150183 ApexM (Predicate) manufactured by InControl Medical, LLC.	ApexMV	Comparison	Impact on Safety and Performance
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 automatically on its own once the session is complete.	The end user can control the electrical stimulation levels and the duration of the stimulation session.	The end user can control the electrical stimulation levels and the starting and stopping of each session. However, the device will automatically stop on its own once the session is complete.	Substantially equivalent to the predicates	None
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, stimulation level settings can only be changed by a Physician or health care provider.	Electrical stimulation levels are set by the end user	Electrical stimulation levels are set by the end user	Identical to ApexM	None
Override	Yes	No	Yes	Identical to InToneMV	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	Over-the-counter device. No special knowledge or training required; instruction manual provided	Over-the-counter device. No special knowledge or training required; instruction manual provided	Identical to ApexM	None
Software Level of Concern	Moderate	Moderate	Moderate	Identical to predicates	None

ApexMV Design Modifications Compared To Predicates

1. The **modifications to the insertion unit** includes: a longer in length inflatable probe of 4.0 inches in place of the 2.7 inch probe on the InToneMV (K134020) device. The inflatable probe is inserted into either the vagina or rectum and manually inflated by the end user to ensure a customized fit. Electrical stimulation is delivered via stainless steel electrodes on the probe to induce a contraction of the pelvic floor muscles. This portion of the device has been modified from the predicate device, InToneMV (K134020).

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2. The attached hand-held control unit includes user keys to initiate and control the treatment sessions. The control unit is designed to provide the stimulation pulses as well as visual biofeedback response. The **modifications to the hand-held control unit** include:
   - Use of a new microprocessor. The stimulation output will operate under the same specifications as the previous InToneMV device (use of the same frequency (13/50Hz), pulse width (200uS), maximum voltage (40V), and maximum current (80mA). The pulse delivery on/off time shall also be identical.
   - The stimulation output characteristics as noted above will be replicated identical to the predicate devices. The electrode surface area of the ApexMV falls between the InToneMV (smaller surface area) and the ApexM (larger surface area) making the ApexMV substantially equivalent in current density compared to the predicates.
   - Addition of an LED indicator that will illuminate when the stimulation is active on the electrodes. The LEDs will only illuminate when sufficient current is conducting from one electrode to another, or will require tissue to bridge between the electrodes (create a current conducing path) in order to illuminate the LEDs.
   - Addition of an OLED display allows users to see the following visual cues:
     - Timer for duration of stimulation session
     - Pressure gauge to illustrate the optimal balloon pressure range to begin the self-directed contractions to maximize the LED biofeedback bar graph response.
     - Visual cues during the self-directed contractions to guide the user when to contract and relax, as well as an integrated timer to illustrate length of contraction/relaxation.
   - Omission of audio, no verbal session guidance will be offered for the ApexMV.

These changes do not change the fundamental technology, operating principle or primary function of the ApexMV device. Software/Firmware verification, electrical safety and EMC testing, Human Factors Usability Study and performance validation was performed in accordance with InControl Medical's risk management process and external standards. A summary of the results from this testing is found in Testing Summary, pages 21-22 of this document.

The table below is a summary of why each predicate was chosen for the ApexMV device design.

Table 7.4: Substantial Equivalence Comparison Table

Attribute	Predicate
Smaller in size Probe	InToneMV
Visual Biofeedback	InToneMV
Over-the-Counter Use	ApexM
Fecal and Urinary Incontinence in men and women	InToneMV
Stress, Urge or Mixed Urinary Incontinence in women	ApexM
End user sets their own stimulation	ApexM

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The ApexMV was designed with the smaller insertion probe, substantially equivalent to the InToneMV to accommodate anal insertion for urinary or fecal incontinence and for certain women who have smaller physical anatomies. The smaller probe aids in either rectal or vaginal insertion. The visual biofeedback that was added to the ApexMV, is substantially equivalent to the predicate, InToneMV. It allows the end user of the ApexMV to visually see the LED bars illuminate when they contract their pelvic floor muscles against the inflated balloon during the self-directed contraction portion of the session, which aids in their treatment.

By combining the smaller probe with the biofeedback, the ApexMV device is then able to treat stress, urge or mixed urinary and/or fecal incontinence in adult women as the electrical technology is identical to the predicates. The over-the-counter use allows the end user to self-diagnose their own incontinence and use the device to specifically treat that incontinence, same as the ApexM. Where as the InToneMV had data review and a controlled treatment session by the clinician/medical professional. The ApexMV doesn't have this data review or controlled treatment session by a clinician/medical professional. The end user of the ApexMV set's their own stimulation as they can with ApexM.

The device labeling and packaging (which includes an educational consumer-focused box, detailed IFU/user manual, laminated quick reference guide/patient card and an instructional video included in the packaging and available via InControl Medical's website) allows the end user to accurately self-diagnose and use the product. ApexMV labeling and packaging is substantially equivalent to the predicate, ApexM (K150183), and is therefore safe for over-the-counter use. This intended use is substantially equivalent to the predicate devices, ApexM (K150183) and InToneMV (K134020). The ApexMV labeling and the predicate labeling for ApexM (150183) and InToneMV (K134020) is found in Appendix 11 – Predicate and ApexMV Labeling.

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Testing Summary

The following testing is provided in support of the substantial equivalence. The testing for ApexMV included software/firmware verification, electrical safety and EMC, Human Factors Usability Study and performance validation, in which the ApexMV device successfully passed all of this testing. Since the ApexMV device uses the same grade, type, color, and manufacturing processes for the silicone parts as the predicates and the previously cleared InTone device (K150180), manufactured by InControl Medical, LLC, the biocompatibility testing was not performed for the ApexMV device to demonstrate the equivalent safety and effectiveness. The biocompatibility testing was previously submitted with the ApexM submission under K150183 and with the InToneMV submission under K134020, there for the data is not attached to this submission for ApexMV.

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 to be a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the end user. Testing data is found in Appendix 4 – Risk Management File.

Electrical Safety and Electromagnetic Compatibility Testing:
Electrical safety and EMC testing was conducted. The ApexMV device complies with the IEC 60601-1, IEC 60601-2-10, IEC 60601-1-11, and IEC 60601-1-2 standards for safety and the standard for EMC. Testing data is found in Appendix 7 – SGS EMC and Electrical Safety.

Biocompatibility Testing:
The biocompatibility evaluation was completed and submitted previously as stated above under the Testing Summary, therefore it was not tested for the ApexMV device. Above, under Testing Summary, contains the rationale. When the biocompatibility testing was performed for the predicates, it 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 the FDA. The inflatable probe on the ApexMV device and predicates is considered tissue contacting for a duration of less than 24 hours. The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Clinical Testing:
A clinical literature evaluation was conducted on the predicates ApexM (150183) and InToneMV (K134020) to provide evidence of the safety and efficacy of electrical stimulation for the treatment of female urinary incontinence and treatment of male urinary or fecal 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.

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A Human Factors Usability Study was conducted on the ApexMV device to assess the safety for over-the-counter use. The Human Factors Usability Study objectives were to: 1) determine if a user/subject can self-identify as having urinary and / or fecal incontinence using package labeling, 2) self-limit usage, if a contraindication is present, 3) safely use the ApexMV device using only package labeling, manual and patient card, and 4) determine subject's ability to complete critical tasks successfully. The study was conducted with collaboration with a supervising physician to ensure the product labeling, IFU, and video provided were suitable for over-the-counter use. The study objectives were met as the subject/end users were able to properly self-identify as having either urinary incontinence (either stress, urge, and/or mixed) or fecal incontinence. The labeling and packaging for the ApexMV device is substantially equivalent to the predicates ApexM (K150183) and InToneMV (K134020). The study feedback supported the availability of a training video. The Clinical Literature Review and Human Factors Usability Study results are found in Appendix 9 – Clinical Literature and Human Factors Usability Study Test.

Risk Management Summary

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

ApexMV has been evaluated for risks according to InControl Medical's internal procedures based on ISO14971. The risks associated with ApexMV were reduced to as low as possible and the risk/benefit analysis was acceptable.

Conclusion

The non-clinical data on the predicate devices support the safety of the ApexMV device. The software verification, performance validation, electrical safety, EMC testing and Human Factors Usability Study demonstrates that the ApexMV device is safe and effective for an over-the-counter treatment of stress, urge, or mixed urinary incontinence and/or fecal incontinence in adult women.