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

Special 510(k) Submission

IN TONE MV JAN - 6 2014

7. 510(k) Summary

Submission Date

December 17th, 2013

Submitter Information

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Device Information

Table 4. Device Information

Type of 510(k):	Special 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

Device Summary

InToneMV is substantially equivalent to the predicate device, InTone (K110179). InToneMV is a modification of the predicate device.

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The InToneMV device includes three parts: an insertion unit, a hand-held control unit, and a PC-based software application. Each of these parts are summarized below, along with a summary of modifications:

- The insertion unit includes (1) an inflation bulb, (2) the inflatable probe, and (3) the flexible tubing connecting the inflation bulb and the probe. The inflatable probe is inserted into the vagina and manually inflated by the patient 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, InTone. The modifications included a smaller probe and a flexible cord between the probe and the inflation bulb.
- The external hand-held control unit includes user keys to initiate and control treatment sessions. The control unit is designed to record and store results of the electrical stimulation and patient generated pelvic floor exercises. There are no modifications to the hand-held control unit; therefore it is identical between InToneMV and the predicate device, InTone.
- The PC-based software application is utilized by the clinician to program the hand-held control unit, store and display the results of electrical stimulation and patient generated pelvic floor exercises. The application allows the clinician to select and lock in the appropriate amount of electrical stimulation necessary to stimulate pelvic floor contraction. There are no modifications to the PC-based software application; therefore it is identical between InToneMV and the predicate device, InTone.

A further description of InToneMV is provided in Section 12 and compares the predicate device, InTone (K110179).

Intended Use

The InToneMV 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 and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

This intended use is identical to the predicate device, InTone (K110179).

Equivalence Comparison to the Predicate

This Special 510(k) submission is for modifications to an existing device, InTone (K110179). Modifications only apply to the insertion unit of the device (no changes are being made to the hand-held control unit or the clinician PC application). The changes to the insertion unit include reducing the size of the probe and adding a flexible cord between the probe and the inflation bulb. InToneMV is substantially equivalent to the predicate device, InTone. The intended use statement of InToneMV is identical to the predicate device, InTone.

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The technical characteristics shared between the two devices is further compared in Section 12.

Testing Summary

The software in InToneMV is identical to the predicate device, InTone (K110179). There have been no modifications to the existing, validated software.

A gap assessment was conducted by Underwriter Laboratories and IEC60601 electrical safety tests were performed on the modifications. Results identified InToneMV as electrically safe.

The patient contact materials used in InToneMV are identical to the predicate device, InTone. There have been no modifications to the materials.

Animal testing was not applicable for InToneMV.

Bench testing of InToneMV is further detailed in Section 13.

Clinical Performance Summary

InToneMV and the predicate device, InTone (K110179), share the same technology and treatment protocol. There have been no modifications to the clinical performance.

Clinical performance of InToneMV is further detailed in Section 14.

Design Control Summary

The modifications of the predicate device, InTone (K110179), have been completed according to InControl Medical's internal procedures and each design change has been verified and/or validated to support InToneMV.

The modifications of the predicate device, InTone, have 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.

The risk management and design controls for InToneMV is further detailed in Section 14.

Conclusion

The modifications to the predicate device, InTone do not impact the safety or effectiveness. The data collected and documented throughout this submission provides objective evidence that InToneMV performs as well as or better than the predicate device for the treatment of female urinary 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

January 6, 2014

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

Re: K133826
Trade/Device Name: InToneMV
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: December 16, 2013
Received: December 17, 2013

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) K133826

Device Name

InToneMV

Indications for Use

The InToneMV 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 and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

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
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