January 16, 2020

Atlantic Therapeutics Ltd.
Anne-Marie Keenan
Quality Regulatory Affairs Specialist
Parkmore Business Park West
Galway, H91 NHT7
IRELAND

Re: K192357
Trade/Device Name: INNOVO®
Regulation Number: 21 CFR 876.5330
Regulation Name: Cutaneous Electrode Stimulator for Urinary Incontinence
Regulatory Class: II
Product Code: QAJ
Dated: December 13, 2019
Received: December 16, 2019

Dear Anne-Marie Keenan:

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,

Jessica K. Nguyen, Ph.D.
Acting Assistant 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)*
K192357

Device Name
INNOVO®

Indications for Use *(Describe)*
The INNOVO® is a transcutaneous electrical stimulator indicated for the treatment of stress urinary incontinence in adult females.

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.

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510(k) Summary

Atlantic Therapeutics Ltd., Parkmore Business Park West, Galway, H91 NHT7, Ireland

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

I. General Information on Submitter:

Submitter Name:	Atlantic Therapeutics Ltd.,
Submitter Address:	Parkmore Business Park West, Galway, H91 NHT7, IRELAND
Contact Name:	Anne-Marie Keenan, QA/RA Specialist
E-Mail Address:	amkeenan@atlantictherapeutics.com
Telephone:	+353 91 412421
Date Prepared:	15th January 2020

II. General Information on Device:

Name of Device:	INNOVO®, Type Number 208
Common Name or Usual Name:	Cutaneous Electrode Stimulator for Urinary Incontinence
Regulation Number:	21 CFR 876.5330
Regulation Name:	Transcutaneous Electrical Continence Device
Regulatory Class:	Class II
Product Code:	QAJ

III. Predicate Devices:

Name of Device:	INNOVO®, Type Number 208 (DEN 170049)
Common Name or Usual Name:	Cutaneous Electrode Stimulator for Urinary Incontinence
Regulation Number:	21 CFR 876.5330
Regulation Name:	Transcutaneous Electrical Continence Device
Regulatory Class:	Class II
Product Code:	QAJ

This predicate has not been subject to a design related recall.

Reference Device:	ELITONE Device (K183585)
Common Name or Usual Name:	Cutaneous Electrode Stimulator for Urinary Incontinence
Regulation Number:	21 CFR 876.5330
Regulation Name:	Transcutaneous Electrical Continence Device
Regulatory Class:	Class II
Product Code:	QAJ

IV. Device Description:

The INNOVO® is a powered transcutaneous electrical continence device intended for the treatment of stress urinary incontinence. The device is provided with an internally wired garment which locates eight conductive electrodes around the pelvic area. An electronic controller, which is attached to the garment using a leadwire, delivers an amplitude modulated symmetric biphasic stimulation current to the electrode array to evoke timed muscle contractions in the pelvic floor muscles. A neck strap clips to the unit to allow it to be worn around the neck. The neck strap contains a safety clip which pops open if there is a forceful pull on the neck strap The current amplitude is adjusted

by the patient using a push-button intensity control. A treatment lasts for 30 minutes and is self-administered by the patient at home. The electronic controller operates from rechargeable batteries and a mechanical interlock is provided to prevent simultaneous connection to the patient and the charger. The INNOVO® is supplied with a non-sterile, electrically conductive, electrolyte spray.

V. Indications for Use :

The INNOVO® is a transcutaneous electrical stimulator indicated for the treatment of stress urinary incontinence in adult females.

Type of Use: Over-The-Counter Use or Prescription Use

The indications for Use Statement has been updated from the predicate to include Over-the-Counter Use.

VI. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices :

The following table summarizes the similarities and differences between the intended use and technological characteristsics of the new device vs. predicate and reference devices.

510(k) Summary

Atlantic Therapeutics Ltd., Parkmore Business Park West, Galway, H91 NHT7, Ireland

Technological Characteristic	INNOVO® (New Device)	INNOVO® (Predicate Device)	Elitone (Reference Device)	Comparison and Impact on Safety and Performance
Indications for Use	The INNOVO® is a transcutaneous electrical stimulator indicated for the treatment of stress urinary incontinence in adult females.	The INNOVO® is a transcutaneous electrical stimulator indicated for the treatment of stress urinary incontinence in adult females.	ELITONE is a non-implanted muscle stimulator designed to treat stress urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding tissues.	Substantially equivalent as the new and predicate devices are intended to treat stress urinary incontinence in women
Type of Use	Rx and OTC	RX	Rx and OTC	Human Factors testing for INNOVO ® has confirmed the new device as safe and reliable for use as OTC.
Therapeutics Modality	Transcutaneous Electrical Continence Device	Transcutaneous Electrical Continence Device	Transcutaneous Electrical Continence Device	Identical
Targeted Tissue	Pelvic floor muscles and surrounding tissues	Pelvic floor muscles and surrounding tissues	Pelvic floor muscles and surrounding tissues	Identical
Anatomic site of stimulation application	Buttocks, lateral pelvis and upper thighs	Buttocks, lateral pelvis and upper thighs	Perineal region	The anatomic site of stimulation application is identical for the new INNOVO® and the predicate INNOVO®. Any differences in anatomic site of stimulation application INNOVO® and Elitone has been established in K183585.
Number of output modes	1	1	1	Identical
No. of output channels	2	2	1	Substantially equivalent (Ref: K183585)
Controls	7 buttons	7 buttons	2 buttons	Substantially equivalent.
Compliance with voluntary standards for electrical safety and EMC.	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2	Identical

510(k) Summary

Atlantic Therapeutics Ltd., Parkmore Business Park West, Galway, H91 NHT7, Ireland

VII. Summary of Non-Clinical Performance Testing:

The INNOVO® has been subjected to non-clinical performance testing as follows;

- IEC 60601-1:2005 & A1:2012 "Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance"
- IEC 60601-2-10:2012 "Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators"
- IEC 60601-1-11:2015 "Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment."
- IEC 60601-1-2:2014 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- IEC 60601-1-6:2010 & A1:2013 (Cons Ed. 3.1) "Medical electrical equipment - Part 1-6: general requirements for basic safety and essential performance - collateral standard: usability"
- IEC 62304:2015 "Medical Device Software - Software Life Cycle Processes
- ISO 14971:2007 "Medical devices - application of risk management to medical devices
- ISO 10993-1:2009 "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process"
- ISO 10993-5:2009 "Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity"
- ISO 10993-10:2010 "Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization"
- ANSI/AAMI/IEC 62366:2015 "Medical devices – Application of usability engineering to medical devices, Part 1"
- AAMI HE75:2009 (Reaffirmed 2013) "Human Factors Engineering – Design of Medical Devices"

Usability Testing – 15 subjects participated in a human factors / usability study to assess the device's suitability for safe over-the-counter use. Key findings included:

(1) participants with diversity in age, education and familiarity with incontinence were able to self-select as appropriate users of the INNOVO® device based on the user labelling,

(2) participants were able to understand the instructions for use and a qualified Human Factors (observer) verified that they correctly self-identified as candidates based on the indications for use and contraindications,

(3) participants were able to apply treatment safely and correctly as for intended use.

VIII. Conclusion

The new and predicate device have the same intended use and any differences in technological characteristics do not raise new issues of safety and effectiveness. Performance testing has demonstrated that the INNOVO® is substantially equivalent to the predicate INNOVO®.