SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Implantable Peripheral Neurostimulator for Incontinence

Device Trade Name: eCoin® Peripheral Neurostimulator System ("eCoin System")

Device Procode: QPT

Applicant's Name and Address: Valencia Technologies Corporation
28464 Westinghouse Pl
Valencia, CA 91355

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200036

Date of FDA Notice of Approval: March 1, 2022

II. INDICATIONS FOR USE

The eCoin® Peripheral Neurostimulator is intended to be used to treat urgency urinary incontinence in patients intolerant to or having an inadequate response to other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation.

III. CONTRAINDICATIONS

Implantation of the eCoin® Peripheral Neurostimulator System ("eCoin System") is contraindicated for the following patients:

- **Poor Surgical Candidates**: The eCoin should not be implanted in patients who are poor surgical candidates. Poor surgical candidates include those who have:
  - Open wounds or sores on the lower leg or foot
  - Had prior surgery in the implant area
  - Had previous, unhealed trauma in the implant area
  - Pitting edema (≥2+) in the lower leg
  - Venous disease/insufficiency in the lower leg
  - Arterial disease/insufficiency in the lower leg
  - Vasculitis or dermatologic conditions in the lower leg
  - Infections near the implantation site in the lower leg
- Patient can not properly operate the Patient Controller Magnets and paper tape for use in the event of unintended or unwanted stimulation.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the eCoin System labeling.

V. DEVICE DESCRIPTION

A. Overview of Device Function and Use

The eCoin Peripheral Neurostimulator System (collectively, the "eCoin System") includes the eCoin Peripheral Neurostimulator ("eCoin"), the External Controller UUI ("External Controller"), and the Patient Controller Magnet and its components. The eCoin is a coin-sized leadless battery-powered implant that stimulates the tibial nerve for the treatment of urgency urinary incontinence in patients intolerant to or having an inadequate response to other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation. The External Controller is a handheld device used to activate and program the eCoin via a magnetic field using a custom access code secured wireless protocol. The External Controller is meant for use by Clinical Staff or Technically Trained Field Persons ("Field Persons"). The Patient Controller Magnet is intended to be held over the implanted eCoin device in the event of undesired or painful stimulation in order to stop or inhibit stimulation output from the eCoin. The eCoin's stimulation output will be inhibited for the entire duration that the Patient Controller Magnet is held over the device

There are three additional components that are used along with the External Controller. These include an AC-DC Adapter used to charge the External Controller, a TECSUN PL-360 World Band Receiver ("Radio") used to confirm activation of the eCoin, and the External Controller – eCoin ("External Controller Magnet") used as an alternative means for a Technically Trained Field Person to stop a triggered stimulation session of the eCoin.

B. Device Components

eCoin Peripheral Neurostimulator ("eCoin"), Model UUI – The implantable neurostimulator is a coin-sized leadless battery-powered device 23 mm in diameter and 3.2 mm thick, hermetically enclosed in a titanium housing. This device delivers current to the tibial nerve through platinum electrodes located along the outer rim and bottom center of the eCoin.

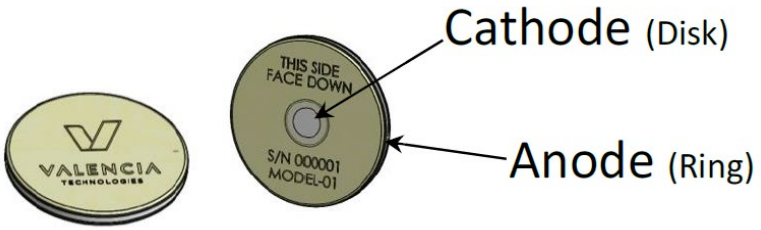


Figure 1: eCoin Peripheral Neurostimulator

The eCoin's stimulation output parameters and battery characteristics are listed below in Table 1.

Table 1. eCoin Peripheral Neurostimulator Stimulation Output and Battery Characteristics

Stimulation Output Characteristics	
Amplitude Range	0.5 to 15mA
Frequency	20 Hz
Pulse Width	0.2 ms
Stimulation Output	Current Controlled
Treatment Duration	30 Minutes
Treatment Interval	3 days for the first 18 weeks (42 sessions) and every 4 days thereafter
Battery Characteristics	
Battery Capacity	75 mAh
Battery Type	Primary, Lithium
Device Life (Moderate Amplitude)	3 Years (Range: 1-8 years)

C. External Controller Components

External Controller UUI ("External Controller") – The External Controller is a hand-held device used to turn the eCoin device on or off and set the stimulation amplitude for ongoing sessions through the use of three push-button switches located on the surface of the component.

External Controller – eCoin ("External Controller Magnet") – The External Controller Magnet is a single Neodymium (NdFeB) permanent magnet. The External Controller Magnet is used as an alternative means for a Technically Trained Field Person to stop a stimulation session that has been initiated by the handheld External Controller. The magnet component is identical to the Patient Controller Magnet. The difference between the External Controller Magnet and the Patient Controller is in who is using it, when it is used, and the outcome. The External Controller Magnet is for the Technically Trained Field Person or Clinical Staff to use to **STOP** a **triggered session**. The patient controller is used by the patient to **INHIBIT** an **automatic session**.

AC-DC Adapter – the AC-DC Adapter is a 5V power supply with a maximum output current of 2 Amperes, rated for input voltages of 100 to 240 Volts. The AC-DC Adapter is used to charge the external controller. The AC-DC adapter may also be plugged into the external controller to power the external controller during programming sessions.

TECSUN PL-360 World Band Receiver ("Radio") - The Radio's Medium Wave (MW) frequency range coverage is from 520 to 1710 kHz. The radio is used by Clinical Staff or Technically Trained Field Persons during programming sessions to confirm activation of the eCoin or determine its ON status during a session.

D. eCoin Surgical Kit

An eCoin Surgical Kit containing the majority of the items needed for implant can be utilized with the eCoin Device Kit. The kit is not required; if not utilized, the implanting physician is expected to provide all tools and equipment. These items include common surgical tools (e.g., surgical marking pen, ruler, 15 blade scalpel, toothed forceps, dissecting scissors, small self-retaining retractor, double-ended skin retractor, needle driver, No. 15 scalpel blades), two custom instruments (**Figure 2**), sterile drape, syringes and needles used for local anesthetic injection, antiseptic prep solution, sterile OR towels, surgical gown, saline flushes, absorbable sutures, Dermabond (skin glue), and a waterproof bandage.

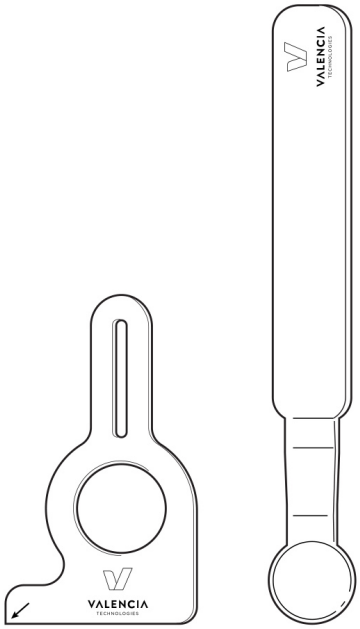


Figure 2: Custom instruments (left to right): marking template and pocket creation tool.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of overactive bladder with urgency urinary incontinence. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his or her physician to select the treatment that best meets their expectations and lifestyle. Patients are typically treated on a treatment continuum starting with the least invasive therapies. Behavioral interventions are the first choice in helping manage overactive bladder (OAB). These include pelvic

floor exercises, maintaining a healthy weight, fluid consumption management, scheduled voiding, and bladder training. When these measures fail or are inadequate for symptom resolution, medications, such as antimuscarinics and β3-adrenoceptor agonists, that promote relaxation of the bladder can provide benefit.

However, these medications may fail to resolve symptoms or may have side effects that can lead to non-compliance. If a patient cannot tolerate drugs or does not experience adequate symptom relief, third line therapies may be prescribed, including Sacral Neuromodulation (SNM) implantation, posterior tibial nerve stimulation, or onabotulinumtoxinA Botox injections.

VII. MARKETING HISTORY

The eCoin Peripheral Neurostimulator System has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device, which are risks beyond those normally associated with surgery, some of which may necessitate surgical intervention:

- Adverse change in storage and/or voiding function (bowel and/or bladder)
- Allergic or immune system response to the implanted materials that could result in device rejections
- Change in sensation or magnitude of stimulation which has been described as uncomfortable (jolting or shocking) by some patients
- Device fracture/failure
- Device inversion or extrusion
- Device migration
- Electrical shock
- Infection
- Pain or irritation at Neurostimulator and/or lead site
- Seroma, hemorrhage, and/or hematoma
- Suspected lead or Neurostimulator migration or erosion
- Suspected nerve injury (including numbness)
- Suspected technical device malfunction
- Transient electric shock or tingling
- Unintended nerve activation
- Heating or burn at Neurostimulator site
- Lack of effectiveness
- Reoperation/Revision
- Undesirable change in pelvic function
- Abscess

- Wound dehiscence
- Edema at the implant or incision site
- Iatrogenic injury to nearby nerves, vessels, or tendons
- Complications associated with the local anesthetic used during the procedure
- Blisters associated with the aftercare materials (ankle wrap)
- Patient use of anticoagulation therapies may increase the risk of procedure-related complications, such as hematomas.
- Skin erosion at the implant or incision site
- Tissue damage at the implant site
- Premature battery depletion

For the specific adverse events recorded in the pivotal clinical study supporting this premarket application, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory testing

The sponsor conducted preclinical bench evaluations of the eCoin component of the system. The results of testing in Table 2 demonstrated the safety and performance of the device. Similarly, results of testing of the External Controller in Table 3, the Radio in Table 4 and system compatibility with other medical components (e.g., electrocautery. MR compatibility, ultrasound and X-Ray imaging procedures) in Table 5, confirmed safety and performance of the device.

Table 2: Summary of key bench testing performed on the eCoin

Test	Test Purpose	Acceptance Criteria
Dimensional Requirements	To verify that the eCoin device meets its dimensional requirements.	The eCoin device mass, thickness, anode ring diameter, exposed width of the anode ring and cathode exposed diameter shall meet specifications.
Stimulation Output	To verify that the stimulation output parameters meet the specifications under various conditions.	The output pulse amplitude, pulse width, and pulse rate shall meet specifications, and the pulse amplitude shall be current regulated.

Test	Test Purpose	Acceptance Criteria
Mechanical Squeeze Test	To verify that the eCoin device does not experience irreversible changes to its function due to being squeezed during use.	The device shall pass its electrical test after being subjected to a mechanical squeeze test, consisting of a 45 N force applied to the center of the device over an area of 0.5 cm^2 for no less than 10 minutes.
Mechanical Shock	To verify that the eCoin device does not experience irreversible changes to its function due to mechanical shock that may occur during implantation. (per ISO 14708-1:2014 Clause 23.7)	The device shall pass its electrical test after being exposed to the mechanical shock conditions of this test.
Random Vibration	To verify that the eCoin device does not experience irreversible changes to its function due to random vibration that it may experience during normal use that includes the time prior to implantation. (per ISO 14708-1:2014 Clause 23.2)	The device shall pass its electrical test after being exposed to the random vibration conditions of this test.
Current Leakage	To verify that the eCoin device is electrically neutral, per ISO 14708-1 Clause 16.2	The direct current density at both the anode and cathode shall be ≤ 0.75 $\mu A/mm^2$.
Hermetic Leak Test	To verify that the eCoin device is hermetically sealed.	The eCoin device shall be hermetically sealed with a helium leak rate of no more than $1x10^{-9}$ atm-cc/sec per MIL-STD-883H, Method 1014.13, Test Condition A4
Water Immersion Test	To verify that the eCoin device remains hermetic after exposure to the environmental test conditions.	The eCoin device shall remain hermetic after immersion in water at a pressure of 2 atm for no less than 24 h.
Battery UL Testing	To verify that the eCoin device battery is safe and reliable as determined by compliance to UL 1642.	The device's battery shall conform to UL 1642.

Test	Test Purpose	Acceptance Criteria
Battery Service Life and Elective Replacement	To verify the service life and elective replacement of the eCoin battery.	PCBA current measurements shall verify that: The eCoin device provides at least 2 years of service life when programmed at its 6 mA setting. The eCoin device provides at least 1 year of service life when programmed at its 15 mA setting.
Accelerated Life Test	To verify that the eCoin Printed Circuit Board Assembly (PCBA) does not experience irreversible changes to its function after a Highly Accelerated Life Test (HALT).	The eCoin PCBA shall pass its electrical test after a 1,000 hour burn-in at 125ºC. The eCoin PCBA shall pass its electrical test after undergoing temperature cycling (10 cycles, -55_{-10}^{+0} ºC to 125_{-0}^{+15} ºC, 10 minute dwell time minimum).
Particulate Count	To verify that the eCoin device does not release unacceptable particulate matter at the time of implantation, per ISO 14708-1:2014 Clause 14.2	The eCoin device shall not have a particle count exceeding 6,000 particles equal to or greater than 10 µm and 600 particles equal to or greater than 25 µm.
Battery External Short Test	To verify that the eCoin device battery generates no more than a 2°C temperature rise at the device surface, in the event of a single fault battery short, when implanted subcutaneously (per ISO 14708-3:2017 Clause 17.1).	The eCoin surface temperature shall not exceed 2°C in the event of a single fault battery short.
Temperature Exposure	To verify that the eCoin device does not experience irreversible changes to its function due to temperature exposure that it may experience during shipping, per ISO 14708-1:2014 Clause 26.2 and ASTM D4332-13.	The device shall pass its functional test after exposure to the temperature conditions of the test, $-10^{\pm3}$°C-$55^{\pm2}$°C.

Test	Test Purpose	Acceptance Criteria
Pressure Exposure	To verify that the eCoin device does not experience irreversible changes to its function due to pressure exposure that it may experience during shipping or use, per ISO 14708-1:2014 Clause 25.1	The device shall pass its electrical test after exposure to the pressure conditions of this test.
Corrosion Test	To verify that the eCoin device is corrosion resistant.	After exposure to the test conditions, the eCoin case, feed through, anode ring and cathode shall not have evidence of corrosion.
Electromagnetic Non-Ionizing Radiation Immunity	To verify that the eCoin device function is maintained during and after exposure to electromagnetic non-ionizing radiation, per ISO 14708-3:2017 Clause 27.	The eCoin device function shall be maintained during and after exposure to electromagnetic non-ionizing radiation. The eCoin device shall not result in an unacceptable risk due to Electromagnetic Interference (EMI).
Electrostatic Discharge	To verify that the eCoin device function is maintained after exposure to electrostatic discharge, per IEC 61000-4-2	The eCoin device shall pass its electrical test after exposure to electrostatic discharge.
Emissions	To verify that the eCoin device emissions are below limits defined by Class B test level/limits, per CISPR 11 Edition 6.0 2015	The eCoin device shall meet the test limits per CISPR 11 Edition 6.0 2015.
Software eCoin Device	To verify that the eCoin device firmware meets the design requirements. NOTE: The level of safety concern for the eCoin device firmware is Moderate since a failure or latent design flaw could directly result in a minor injury to the patient by leading to uncomfortable levels of stimulation and/or the need for premature device explant.	The eCoin software shall meet all specified requirements.

Table 3: Summary of key bench testing performed on the External Controller

Test	Test Purpose	Acceptance Criteria
External Controller Output	To verify that the external controller meets all output command and command data transmission and timing requirements.	The buttons pressed on the external controller correspond to the correct transmissions by the controller.
External Controller Battery Discharge and Charge Time	To verify that the external controller battery discharge and charge time meet the needs of the Technically Trained Field Person or Clinical Staff to program the eCoin device.	The external controller provides at least 7 days of standby operation and 15 minutes of transmit operation on a single battery charge. The external controller charging, with a fully discharged battery, completes within 6 hours.
External Controller Battery Safety Testing	To demonstrate the safety of the external controller battery.	The external controller battery shall comply with IEC 62133:2012. The battery protection circuitry for over-charging, over-discharging, and over-heating were verified to operate as specified. Battery short-circuit protection was verified to operate as specified.
External Controller IEC 60601-1 Tests	To demonstrate that the external controller meets the requirements of IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	The external controller shall meet the requirements of all applicable sections of IEC 60601-1
External Controller IEC 60601-1-2 and CISPR 11 Tests	To verify that the External Controller UUI meets the requirements of IEC 60601-1-2.	The external controller shall pass immunity testing, per IEC60601-1-2. The external controller shall not exceed emissions limits.
Software External Controller	To verify that the external controller firmware meets the design requirements. NOTE: The level of safety concern for the External Controller firmware is Minor	The external controller shall meet all requirements specified in its functional specifications.

Test	Test Purpose	Acceptance Criteria
	since its function is limited such that a failure or design flaw is unlikely to cause any injury to the patient or operator.	

Table 4. Summary of bench testing performed on the Radio

Test	Test Purpose	Acceptance Criteria
Radio Use Verification	To verify the TECSUN PL-360 receiver use for the purposes of determining whether an eCoin device is on.	The radio receiver operator shall be able to confirm whether the eCoin device is on up to 15mm from the eCoin at all amplitudes. The users shall be able to accurately and reliably determine whether an eCoin device is on during activation and during a triggered session.
Radio Interference Test	To verify that sources of radio frequency interference do not affect the radio receiver user's ability to confirm an eCoin device activation and the active use of an ongoing device triggered session.	The radio receiver operator shall be able to correctly determine the ON status of the eCoin device while the eCoin device is operating nearby sources of radio interference.
Radio Receiver IEC 60601-1 Tests	To verify that the Radio Receiver meets the requirements of IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	The Radio Receiver shall meet the requirements of all applicable sections of IEC 60601-1
Radio Receiver IEC 60601-1-2	To verify that the Radio Receiver meets the requirements of IEC 60601-1-2.	The Radio Receiver shall meet all applicable clauses of IEC 60601-1-2

B. <u>Medical Procedure Compatibility</u>

Testing was performed on the eCoin System for compatibility with electrocautery, diagnostic ultrasound, and diagnostic X-ray exposure. Key system testing is summarized in Table 5 below. All test articles met all functional requirements of

the testing after exposure to medical therapy conditions, passing this preclinical testing and verifying that the eCoin meets requirements for compatibility with these therapies.

The eCoin was also tested for compatibility with magnetic resonance imaging (MRI) using a head coil with 1.5T and 3T scanners. The device is labeled as MR conditional.

Table 5. Summary of Medical Compatibility Tests

Test	Test Purpose	Acceptance Criteria
Electrosurgery Immunity	To verify that the eCoin device does not experience irreversible changes to its function caused by electrosurgery applied no closer than 25 cm from the device.	The eCoin device shall pass its electrical test after exposure to the conditions of the test.
MR Compatibility with 1.5T and 3T Head Coil	To verify that eCoin is MR Conditional compatible and MR conditional can be safely performed.	The eCoin device shall meet the acceptance criteria for MR Conditional when used outside an MRI system with a static magnetic field strength of 1.5 T or 3.0 T. The implanted device must be outside of the bore of the MR machine by at least 20 cm.
Diagnostic Ultrasound	To verify that diagnostic ultrasound can be safely performed.	The eCoin device shall pass its electrical test after exposure to diagnostic levels of ultrasound, per ISO 14708-1:2014 Clause 22.1.
X-Ray Compatibility	To verify that the radiopaque label is legible under X-ray. To verify that diagnostic X-rays can be performed in the region with the device implanted without irreversible effects on the device.	The eCoin device radiopaque label shall be clearly legible under X-ray. The eCoin device shall pass its electrical test after being exposed to X-ray radiation. The eCoin device shall cause minimal to no distortion of the anatomical features adjacent to the device.

C. Human Factors and Usability

An assessment of the Human Factors and Usability of the eCoin surgical procedure was performed. During this testing, 37 participants were observed to see if they performed a use error during a simulated implant/revision surgery. This simulated surgery required the participant to execute 38 individual surgical

tasks. Test participants were provided with online, didactic and practicum training before executing this validation test.

The one critical task for the eCoin surgical procedure is during the device insertion task where the subtask was to identify the fascial layer and then dissect above the fascial layer. The use error of concern was if a physician did not correctly identify the fascial layer, subsequently violated it, and did not recognize the violation and used the blunt dissector tool below the fascia. This use error could potentially result in damage to deep structures below the fascial layer.

In total, 1,406 surgical tasks were performed by the 37 test participants. Eighteen non-critical use errors were observed during the execution of these 1,406 surgical tasks resulting in an overall error rate of 1.3%.

Key facts regarding the observed use errors:

- There were no occurrences of the critical use error where the blunt dissection tool was used BELOW the fascia. There was a single critical use error that was identified for this validation test. There were three cases in which a user began dissection of the fascia; however, the user recognized the potential violation and corrected their surgical approach.
- There were no use errors associated with positioning of the device.
- There were no use errors that would result in damage to surrounding structures.

The most common errors occurred in the suturing steps (5 errors were associated with deep dermis closure, 1 error in subcutaneous closure and 1 error in epidermis closure). One potential root cause from the interview data was the need for participants to have more practice suturing. Also, the training may need to provide additional details regarding suture technique, distance between stitches, type of thread to use, etc. As a result of this testing, more detail has been provided in the physician manual regarding suturing.

Another potential root cause is that the simulated surgeries were performed on cadaver legs. A limitation of cadaver training includes suturing tissue not completely representative of live human flesh. Tissue layers may be compromised depending on the quality of the specimen. In addition, the more limited ergonomics of a cadaver lab such as fixed table heights, absent surgical stools and reduced lighting options might impair the caliber of a precise multi-layer closure compared to suturing performed at an actual medical facility.

Additional risk reduction measures to address these errors include a requirement that implanting physicians must first undergo three proctored surgeries before they can perform an implant solo. During these proctored surgeries, they will receive feedback in real time on their suturing technique. The proctoring of cases in a surgeon's normal working environment with actual patients will reinforce proper incision closure. In addition, all closures will be logged in a photo database

with careful evaluation of initial implants within 48 hours. Should photos from this database suggest poor surgical technique, the implanting physician must go through some remediation and then be re-evaluated for certification to implant eCoin.

D. Biocompatibility

Biocompatibility testing was performed for all patient-contacting components of the eCoin System in accordance with ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, on the finished sterilized devices. All biocompatibility studies were conducted in compliance with Good Laboratory Practices (GLP), 21 CFR Part 58.

The eCoin device is considered a permanent (> 30 days) implant in contact with tissue/bone. The following biocompatibility endpoints were assessed for this device component:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Sub Chronic Systemic Toxicity
- Genotoxicity
- Implantation 90 Day
- Material-Mediated Pyrogenicity
- Biological Risk Assessment

The external controller is considered a surface device, in contact with intact skin for a limited duration (≤ 24 hrs). The following biocompatibility endpoints were assessed for the external controller: cytotoxicity, sensitization and irritation/intracutaneous reactivity. The Patient Controller Magnet is covered by a silicone sleeve which prevents direct skin contact. The material was assessed for cytotoxicity and sensitization.

All pre-specified test acceptance criteria were met, and all tests passed.

E. Sterility

The eCoin System components that are provided sterile are terminally sterilized using a 100% ethylene oxide (EO) sterilization process to provide a minimum sterility assurance level (SAL) of 10^{-6}. Validation of the sterilization process is in compliance with ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices. Sterilant residuals conform to the maximum allowable limits of EO and ethylene chlorohydrin (ECH) residuals specified in ISO 10993-7:2008, Biological

Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. The product bacterial endotoxin limits are based on FDA's Guidance for Industry - Pyrogen and Endotoxins Testing: Questions and Answers (June 2012) and were verified using Limulus Amebocyte Lysate (LAL) testing.

F. Packaging and Shelf Life

Packaging tests were completed in compliance with ISO 11607-1:2009 Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems. Packaging materials were able to withstand the rigors of shipping and distribution to maintain product sterility. Shelf life was assessed through real-time aging testing which included packaging and device functionality assessments. Shelf life for the sterile system components has been established as 12 months from the date of manufacturing.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

Valencia Technologies performed a pivotal study, under Investigational Device Exemption (IDE) G170301, to evaluate the safety and effectiveness of the eCoin System in the treatment of urgency urinary incontinence (UUI). Data from this study were the primary basis for the PMA approval decision. The pivotal study was conducted in 15 US clinical sites and evaluated 133 patients. A summary of the clinical study is presented below.

A. Study Design

The study was a prospective, multicenter, single-arm trial to evaluate the safety and effectiveness of the eCoin System in subjects with urgency urinary incontinence (UUI). Across 15 sites, 133 subjects were enrolled starting August 28, 2018, with the final implant occurring on April 12, 2019. Procedures were performed primarily in office settings and all under local anesthetic. The study evaluated changes from baseline in UUI episodes as measured by voiding diaries and patient-reported outcomes through 48 weeks of eCoin therapy (which is equivalent to 52 weeks from device implantation). Patients who achieved at least a 50% improvement in the number of UUI episodes as measured in a 3-day voiding diary were considered therapeutic successes ("responders"). The primary effectiveness endpoint was the proportion of responders after 48 weeks of therapy. The 3-day voiding diaries were self-reported and documented at least 3 days prior to the follow-up visit. The key secondary effectiveness endpoint was the proportion of patients achieving at least a 50% improvement in the number of UUI episodes per 24 hours on a 3-day voiding diary ("responder rate") after 24 weeks of therapy.

The primary safety endpoint was to assess device-related adverse events from implantation (or attempted implantation) to 52 weeks after implantation of eCoin.

The secondary safety endpoint was to assess the same at 28 weeks after implantation.

In the clinical investigation, eCoin candidates were assessed for eligibility with confirmation of an UUI diagnosis. Subjects were enrolled by confirmation of UUI by use of voiding diaries. In addition, subjects were provided a transcutaneous electrical nerve stimulation (TENS) device pre-implantation which matched the electrical paradigm of eCoin, i.e., pulse width and frequency but with amplitude adjusted by the patient. Use of the TENS unit pre-operatively was to determine if subjects responding to TENS treatment might predict responders to eCoin treatment. However, no subjects were excluded based on a screening test or trial procedure. Candidates then underwent implantation of the eCoin device in the medial lower leg above the fascia, under local anesthetic. An incision and healing check was performed about 2 weeks after the procedure. Generally occurring four weeks after implantation with minimal swelling confirmed, Technically Trained Field Persons or Clinical Staff activated (turn ON and SET) the device at a programming visit. The pulse amplitude (0.5-15mA) was adjusted with an external controller to an acceptable sensory level. The amplitude was set at an initial level where the subject felt sensation in the foot or set at a nominal initial level of 8 mA in cases where the subject did not feel a sensation at any amplitude. Automated stimulation sessions occurred for 30-minute durations every three days for 18 weeks and every four days thereafter; all changes to programming were performed by Technically Trained Field Persons or Clinical Staff.

A Data Safety Monitoring Board (DSMB) monitored the study.

1. Clinical Inclusion and Exclusion Criteria

   Inclusion Criteria
   Women and men between the ages of 18 and 80 years of age with a diagnosis of overactive bladder (OAB) with urgency urinary incontinence or mixed urge and stress incontinence with a predominant urgency component (self-reported), for at least 6 months were enrolled in the study. In addition, to be enrolled an individual had to have at least one urgency urinary incontinence episode on each of three days as documented in a 3-day voiding diary. For the study, individuals had to be without pharmacological treatment of OAB (antimuscarinics and β3-adrenoceptor agonists) for 2 weeks prior to their baseline determinations or that the individual was intolerant of, or had an inadequate response to, any of antimuscarinics, β3-adrenoceptor agonists, or onabotulinumtoxinA. Subjects who had previous experience with percutaneous tibial nerve stimulation were also enrolled.

   Exclusion Criteria
   Subjects were excluded if they had predominantly stress urinary incontinence with more than one-third stress urinary incontinent episodes when compared to total urinary incontinent episodes, and if they had urological or

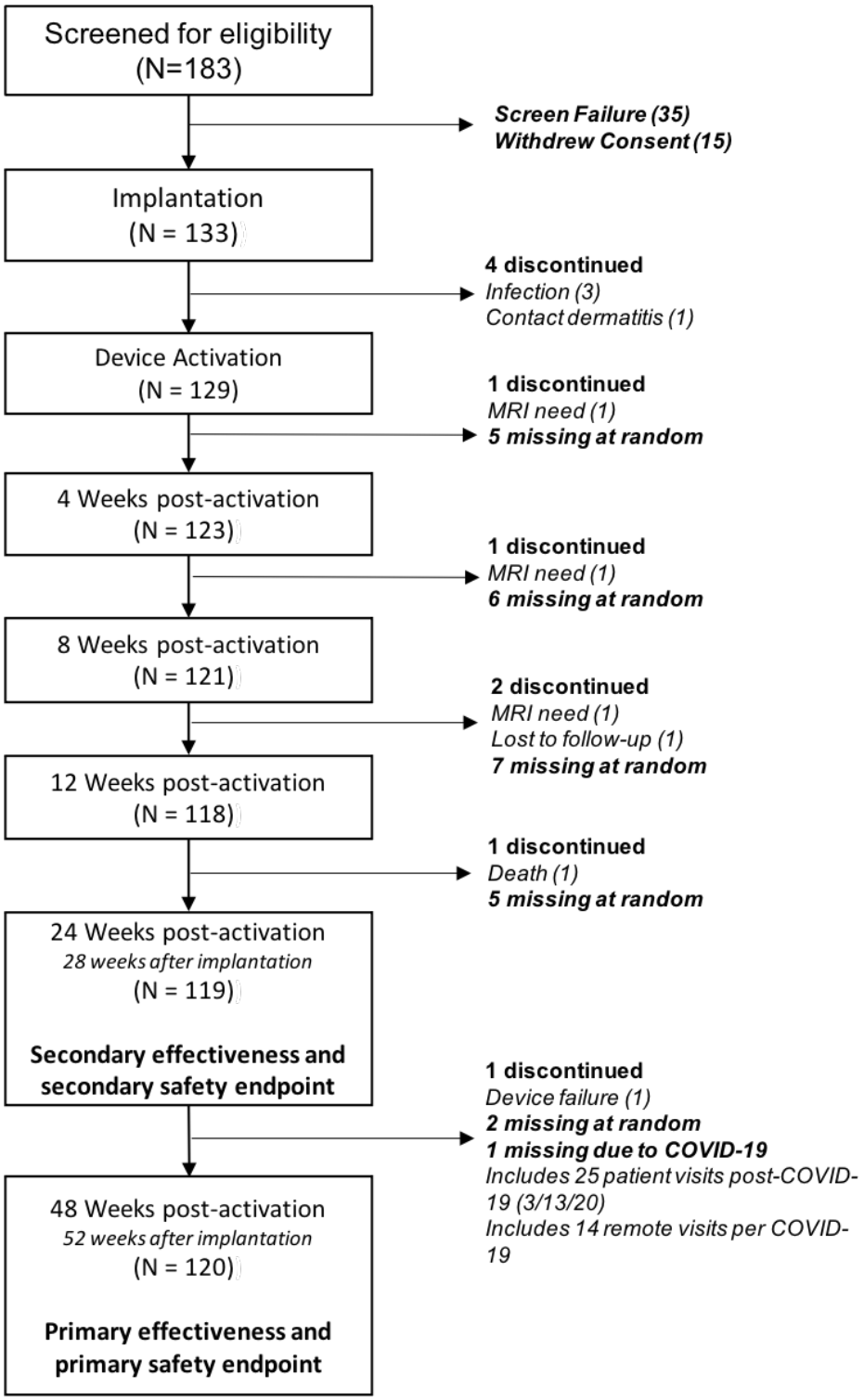
urogynecological structural abnormalities, e.g., bladder outlet obstruction, pelvic organ prolapse (POP). Other exclusion criteria included prior surgical procedures for incontinence, subjects with interstitial cystitis, bladder pain syndrome and urinary tract infections (UTIs). Subjects with peripheral artery disease (PAD), chronic venous insufficiency (CVI), morbid obesity, uncontrolled diabetes, cancers of the urogenital tissues, and blood clotting disorders were also not enrolled. Individuals with neuropathies, who have implanted stimulators, or who have had treatment with sacral nerve stimulation or drug (onabotulinumtoxin A) were not enrolled.

2. Follow-Up Schedule

All patients were scheduled to return for an implant healing check 2 weeks after implantation, and an additional healing check and device activation 4 weeks after implantation. Once the device was activated, all patients were scheduled to return for follow-up examinations at 4, 8, 12, 24, 36, and 48 weeks. Adverse events and complications were recorded at all visits through 48 weeks post-activation of the eCoin device (52 weeks post-implantation). All analyses supporting this clinical investigation were complete at 52 weeks post-implantation. Subjects had the option of consenting to up to an additional 2 years of follow-up with annual study visits to collect longer term data.

Preoperatively, the patients completed a post-void residual (PVR) assessment and urinalysis. At each visit, the patients completed a voiding diary, patient reported outcome questionnaires such as the Overactive Bladder Symptom Quality of Life Questionnaire (OABq) and Patient Global Impression of Improvement (PGI-I) questionnaire as well as a custom patient satisfaction survey.

A flow-chart summarizing the follow-up schedule, including the timepoints for each assessment and patient accountability at each time point, can be found in Figure 3 below.



Missing at random = Data for this participant is unavailable for listed visit below ONLY. No cumulative effect.

Figure 3: Flow-chart of Follow-up Schedule

3. Clinical Endpoints

Primary Safety – assessment of device-related adverse events from implantation to 52 weeks after implantation of eCoin.

Primary Effectiveness – to assess the effectiveness of eCoin after 48 weeks of therapy. Effectiveness was defined as having a ≥50% reduction in UUI episodes per 24 hours on a 3-day voiding diary.

Secondary Endpoints included:

Safety – assessment of device-related adverse events experienced from implantation to 28 weeks after implantation of eCoin.

Effectiveness – to assess the effectiveness of eCoin on the proportion of responders after 24 weeks of therapy.

Other secondary objectives are based on data after 24 and 48 weeks from activation (28 and 52 weeks after implantation). These assessments were for descriptive purposes and were not hypothesis driven.

- Proportion of subjects achieving 75% improvement in the number of UUI episodes per 24 hours on a 3-day voiding diary
- Proportion of subjects achieving 100% improvement in the number of UUI episodes per 24 hours on a 3-day voiding diary
- Change in patient-reported overactive bladder condition utilizing the Patient Global Impression of Improvement (PGI-I) questionnaire
- Patient-reported satisfaction with eCoin therapy utilizing the custom patient satisfaction rating survey

B. Accountability of the PMA Cohort

At the time of database lock, 137 patients had been enrolled in the clinical study. 1 patient withdrew consent, 1 patient exhibited significant non-compliance, 2 patients were not implanted given achievement of the recruitment goal. The remaining 133 patients were implanted, inclusive of zero failed attempted implantations, with the eCoin and were considered the intent-to-treat (ITT) population. Of the 133 implanted patients, 119, 122 and 120 attended the 24-week, 36-week, and 48-week visits including remote 48-week visits. A flow-chart summarizing the ITT population can be found in **Figure 4** below. Eight subjects were implanted but later determined to be ineligible with regard to the inclusion and exclusion criteria. These subjects remain in the ITT population but are excluded from the per protocol (PP) analysis population.

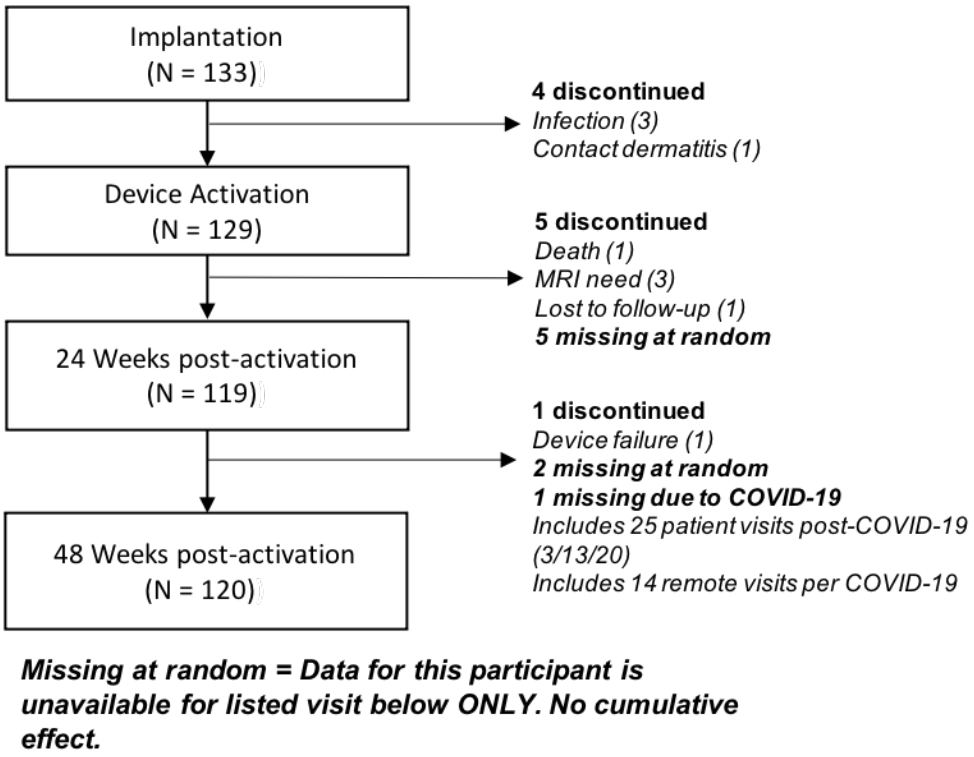


Figure 4: Accountability of PMA Cohort

C. Study Population Demographics and Baseline Parameter

The demographics of the study population are provided in Table 6 below.

Table 6: Demographics – all implanted subjects

Demographics	Total (N = 133)
Age (years) at enrollment	
N	133
Mean (SD)	64.0 (11.0)
Range (min, max)	30, 80
Quartiles (25th, median, 75th)	59, 66, 72
Female, n/N(%)	131/133 (98)
Current smoker, n/N(%)	1/133 (1)
Race, n/N(%)	
White	112/133 (84)
Black or African American	6 (5)
American Indian or Alaska Native	3 (2)

Asian	2 (2)
Native Hawaiian or Other Pacific Islander	1 (1)
Not checked	9 (7)
Ethnicity	
Not Hispanic or Latino	101/133 (76)
Hispanic or Latino	22 (17)
Not known	10 (8)

Abbreviations: SD, standard deviation.

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the ITT population, which included 133 subjects implanted with the eCoin with follow-up through 52 weeks. On average, subjects had a permanent implant for 50.7 weeks.

The primary safety endpoint was to assess device-related adverse events 52 weeks after implantation of the eCoin. The secondary safety endpoint was to assess device-related adverse events 28 weeks after implantation of the eCoin. Device and procedure-related adverse events are provided as exploratory analyses.

Among the 133 implanted subjects, 18 subjects (14%) had serious adverse events. Four (3%) serious adverse events were related to the device or procedure. A total of 27 subjects (20%) had device or procedure-related AEs.

Among the 133 implanted subjects, 52 weeks after implantation of the eCoin, a total of 23 subjects (17%) reported a device-related adverse event. For each time window (28 and 52 weeks from device implantation), 27 subjects (20%) of implanted patients reported at least one treatment-emergent AE related to the study device and/or procedure. Eighteen (18) subjects (14%) had serious adverse events, 4 (3%) subjects reported serious adverse events related to the device or procedure. At 48 weeks, in an exploratory analysis, no patients reported severe stimulation pain.

Table 7: Overall Summary of Adverse Events in All Implanted Subjects

Subjects with Adverse Events	N=133 Up to 52 Weeks Subjects (%)
Subjects with Any Adverse Events	79 (59)
Subjects with Any Procedure or Device-related adverse events	27 (20)
Subjects with Serious adverse events	18 (14)
Procedure or Device-related serious adverse events	4 (3)
Subjects with Non-serious adverse events	74 (56)
Procedure or Device-related non-serious adverse event	25 (19)

Serious Adverse Events

Table 8 lists all serious adverse events (SAEs). There were four related serious adverse events—three infections and one contact dermatitis resulting in explant of the device. Of the four serious adverse events, two were deemed severe, one implant site infection and one postoperative wound infection. All other serious adverse events were unrelated to device or procedure.

Table 8: All Serious Adverse Events – All Implanted Subjects

Medical Dictionary for Regulatory Activities (MedDRA) Terminology: System Organ Class/Preferred Term	Total N=133 N (%)
Subjects with serious adverse events	**18 (14)**
Nervous	**3 (2)**
Encephalopathy	1 (1)
Hydrocephalus	1 (1)
TIA	1 (1)
Cardiac	**3 (2)**
Atrial fibrillation	1 (1)
Left ventricular failure	1 (1)
MI	1 (1)
Infections	**3 (2)**
Implant site infection	2 (2)
Postoperative wound infection	1 (1)

Skin	**1 (1)**
Dermatitis contact	1 (1)
Surgical and medical	**4 (3)**
Hysterectomy	1 (1)
Knee arthroplasty	3 (2)
GI	**1 (1)**
Alcoholic pancreatitis	1 (1)
General	**1 (1)**
Chest Pain	1 (1)
Hepatobiliary	**1 (1)**
Cholecystitis acute	1 (1)
Injuries	**1 (1)**
Fall	1 (1)
Reproductive system	**1 (1)**
Female genital tract fistula	1 (1)

Only AEs that occurred within 52 weeks after implantation are shown.

Deaths

There was 1 study subject death. The subject died as a result of an acute cardiovascular event unrelated to the device or procedure.

All Adverse Events and Related Adverse Events

Table 9 provides a summary of all related adverse events, both serious and non-serious, through 52 weeks. Among the 133 subjects, a total of 27 subjects (20%) had device or procedure-related AEs. The most frequent were device stimulation issues occurring in 6 subjects (5%), and infection, occurring in 9 subjects (7%). Of the related events, 4 subjects (3%) were explanted and the event was resolved. During the study, eight patients total were explanted: 4 due to related adverse events (3 infection, 1 contact dermatitis), 3 for an MRI need, and 1 for device failure. One subject was revised for device dislocation. The majority of related events were mild in grade, with three graded severe. Severity was determined by the investigator and study site, not by the sponsor. Serious nature of an AE was determined by a clinically acceptable, pre-specified definition. Among the 133 subjects, 79 subjects (59%) reported adverse events through 52 weeks. Two subjects with related SAEs also had related non-serious AEs.

Table 9: Study-Related Adverse Events in the Intent-to-Treat Population through 52 Weeks

MedDRA Preferred Term	Non-Serious Study Related Subjects (%)	Serious Study Related Subjects (%)
Subjects with adverse events related to study device or procedure	**25 (19)**	**4 (3)**
Infections	**7 (5)**	**3 (2)**
Postoperative wound infection	5 (4)	1 (1)
Implant site infection	1 (1)	2 (2)
Wound abscess	1 (1)	0 (0)
Product Issues	**10 (8)**	**0 (0)**
Device stimulation issue	6 (5)	0 (0)
Device dislocation	2 (2)	0 (0)
Device malfunction	2 (2)	0 (0)
Injuries	**6 (5)**	**0 (0)**
Wound dehiscence	2 (2)	0 (0)
Incision site erythema	1 (1)	0 (0)
Incision site pain	1 (1)	0 (0)
Wound	1 (1)	0 (0)
Ligament sprain	1 (1)	0 (0)
Musculoskeletal	**2 (2)**	**0 (0)**
Musculoskeletal discomfort	1 (1)	0 (0)
Pain in extremity	1 (1)	0 (0)
Skin	**1 (1)**	**1 (1)**
Dermatitis contact	0 (0)	1 (1)
Skin irritation	1 (1)	0 (0)
GI	**1 (1)**	**0 (0)**
Anal incontinence	1 (1)	0 (0)

2. Effectiveness Results

The intent-to-treat (ITT) analysis of effectiveness is based on the 133 evaluable subjects at 24, 36 and 48-weeks post-activation. The intent-to-treat population consists of all subjects who underwent a procedure for

implantation of the eCoin device. The per protocol analysis of effectiveness is based on the 108 subjects at 48-weeks post-activation who did not have a major protocol deviation or take medications for overactive bladder during the course of the study. No imputation was done in the per protocol population.

All of the 133 subjects in whom an eCoin device was implanted or attempted to be implanted are included in the ITT population. All patients in whom an implant was attempted were implanted.

All subjects explanted, except those explanted for MRI, were treated as non-responders for any missing primary endpoint assessments. Subjects who had their device explanted for MRI had their missing data imputed. Any subjects for whom data was missing and the investigator did not know whether or not the device was in place were to be treated as non-responders. Subjects with missing data who are known by the investigator to have their device in place were assumed missing at random and handled with multiple imputation. All subjects undergoing a procedure, whether or not the device was activated, were to be treated as if the device was activated. One patient with a baseline UUI value of zero was treated as a non-responder.

The primary effectiveness endpoint was the ITT responder rate where responder is defined as a subject improving by at least 50% in their UUI episodes as compared to their own baseline at 48 weeks, post-implantation. The study primary effectiveness endpoint showing a 68% responder rate at 48 weeks (95% CI, 60, 76). At 24 weeks, 69% of all subjects were responders in the ITT population. In the per protocol population, 75% of subjects were responders.

Table 10: Primary Effectiveness Endpoint: ITT population

	Proportion of Responders (SE) *N = 133*	*95% CI*
Primary effectiveness endpoint		
48 weeks of stimulation	**133**	
Responder rate, with responder defined as subjects showing ≥50% reduction from baseline in the number of UUI episodes	68 (4)	60, 76

Abbreviations: CI=Confidence Interval; SE=Standard Error; UUI=urgency urinary incontinence

The key secondary effectiveness endpoint was the responder rate at 24 weeks post-activation in the ITT population. At 24 weeks, 69% (95% CI, 61, 77) of subjects were responders. Additionally, 43% of subjects had 75% or greater

reduction in their urgency urinary incontinence episodes at 48 weeks, and 21% of people showed 100% resolution of their UUI (dry).

The patient reported outcomes included the PGI-I, the OABq, and a custom satisfaction questionnaire. Patient outcomes are summarized in the ITT population. The OABq and PGI-I secondary endpoint results at 24 and 48 weeks are summarized below in Table 11 and 12. Additionally, 77% and 81% of subjects reported feeling at least better on the PGI-I at 24 and 48 weeks, respectively, with 34% and 39% of all subjects reporting the best possible score of "very much better." On the custom satisfaction question rating satisfaction from completely satisfied to not at all satisfied, 61% and 63% of subjects reported being very or completely satisfied with the eCoin at 24 and 48 weeks, respectively.

Table 11: Patient Reported Outcomes: ITT population (all available data)

OABq **Baseline and Change from Baseline at 24 and 48 Weeks**	**N**	**Mean (SD)**	**Quartiles (25^{th}, median,75^{th})**	**Range (min, max)**
Baseline Symptom Bother	128	66.1 (19.6)	55, 65, 80	18, 100
24 Weeks Symptom Bother Change from Baseline (*decrease is better*)	116	-33.4 (26.8)	-55, -35, -14	-93, 23
48 Weeks Symptom Bother Change from Baseline (*decrease is better*)	116	-34.2 (27.5)	-55, -34, -14	-95, 33
Baseline Health Related Quality of Life (HRQoL)	128	45.7 (22.5)	29, 48, 62	0, 95
24 Weeks HRQoL Change from Baseline (*increase is better*)	116	+33.6 (27.6)	14, 32, 54	-25, 98
48 Weeks HRQoL Change from Baseline (*increase is better*)	116	+34.5 (25.9)	13, 33, 57	-15, 89

Table 12: Patient Reported Outcomes: ITT population (all available data)

Patient Global Impression of Improvement in Incontinence at 24 and 48 Weeks (*scale 1-7, lower is better*)	**N**	**Mean (SD)**	**Quartiles (25^{th}, median, 75^{th})**
"Compared to how the subject's urinary leakage was before treatment, subject now reports that he or she feels" *1 – very much better* *2 – much better* *3 – better* *4 – about the same* *5 – worse* *6 – much worse* *7 – very much worse*			
24 Weeks	122	2.4 (1.3)	1, 2, 3
48 Weeks	120	2.3 (1.4)	1, 2, 3

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 15 investigators of which six had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: none;
- Significant payment of other sorts: one;
- Proprietary interest in the product tested held by the investigator: none;
- Significant equity interest held by investigator in sponsor of covered study: six.

Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. In review of effectiveness and safety outcomes at the 6 investigational sites that reported

significant payment and significant equity interest, differences in patient outcomes were noted when compared to sites without financial disclosure. FDA determined the information provided did raise questions about the reliability of the data. The following additional actions were taken and deemed necessary to ensure the reliability of the data (21 CFR 54.5(c)): an inspection of 4 selected sites (3 with financial interests, 1 without financial interests) and the sponsor's headquarters was conducted by FDA's Bioresearch Monitoring (BIMO) program. Observations of adverse event reporting and clinical study conduct were noted and rectified by revisions to the study data and remedial training. BIMO determined that the financial interests did not affect the integrity of the safety and effectiveness outcomes of the study. Further, FDA has requested that the applicant conduct a post-approval study to confirm the results of the pivotal study.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology/Urology Panel, an FDA advisory committee, for review and recommendation, because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

1. Effectiveness Conclusions

Effectiveness of the eCoin System was based upon the 133-subject prospective, multi-center pivotal study in the United States.

The eCoin System demonstrated clinically meaningful improvements in incontinence, marked by a 68% responder rate at 48 weeks (95% CI, 60, 76). Patients with mean baseline UUI episodes of 4.32 (SD 3.08) as reported in bladder diaries improved by a mean reduction of 2.61 (SD 2.97). Clinically meaningful improvements in incontinence were also seen at the secondary endpoint of 24 weeks, with a 68% (95% CI, 60, 77) responder rate.

2. Safety Conclusions

Risks associated with the device are based on nonclinical studies and the eCoin pivotal study. Through 52 weeks of follow up, 17% of patients reported device-related adverse events, and 20% of patients reported device- or procedure-related adverse events. Most events were mild and only four related adverse events were serious (resolved by explantation without sequelae). The procedure, performed under local anesthetic, was well-tolerated by patients.

3. Benefit-Risk Determination

The probable benefits of the eCoin System are based on data collected in the pivotal clinical study. Effectiveness was demonstrated by improvements in urgency urinary incontinence (UUI) from baseline as measured by voiding diaries and responder rate at 48 weeks post-implantation. Potential benefits include a less complicated surgical implantation of eCoin than SNM devices, as well as an improvement in patient compliance than other treatments, such as percutaneous tibial nerve stimulation (PTNS) which involves repeated clinical office visits.

The probable risks associated with the use of the eCoin System are based on data collected in the pivotal study. The adverse events reported were consistent with legally marketed neuromodulation systems. The pivotal study data up to 52 weeks of follow up showed a very low incidence of SAEs and a low incidence of mostly mild, anticipated AEs, such as device stimulation issues and infection. Additional risks include the need for replacement of the device due to the battery's lifespan and the uncertainty of the study data. The study observed the need to re-implant the device after only 1 year. Safety of explantation and reimplantation is not known but will be a focus of a Post-Approval Study (PAS). There is uncertainty regarding the clinical data since the study design lacked a control comparator cohort and the performance goal was identified after patients had already been implanted. The PAS will provide greater certainty of the potential benefit of the device.

1. Patient Perspective

   Patient perspectives considered during the review included:
   - Patient reported outcome measures (PRO) on how a patient feels or functions
   - Information that captures relative desirability or acceptability of outcomes or other attributes that differ among alternative health interventions to patients, the value patients place on the treatment or diagnosis.

In conclusion, given the available information above, the data support that for the treatment of urgency urinary incontinence in patients intolerant to or having an inadequate response to other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation the probable benefits outweigh the probable risks.

4. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use and labeling. The evidence supporting the safety and effectiveness of the eCoin system includes a 133-subject prospective, multicenter clinical trial in the United States following patients through at least 52 weeks. The results from non-clinical and clinical testing show that the eCoin System performs as intended. The analyses also support a favorable clinical benefit to risk determination.

XIII. CDRH DECISION

CDRH issued an approval order on March 1, 2022. The final clinical conditions of approval cited in the approval order are:

1. Continued Follow-Up of G170301 Clinical Study. The "Pivotal Study of Subcutaneous Tibial Nerve Stimulation with eCoin® for OAB with Urinary Urge Incontinence" (G170301) was initiated prior to device approval and is a single-arm, multi-center clinical study which enrolled 133 subjects. The study was designed to evaluate changes from baseline in UUI episodes as measured by voiding diaries and patient-reported outcomes through 48 weeks of eCoin therapy (which is equivalent to 52 weeks from device implantation). Patients who achieved at least a 50% improvement in the number of UUI episodes as measured in a 3-day voiding diary were considered therapeutic successes ("responders"). The primary effectiveness endpoint was the proportion of responders after 48 weeks of therapy. You must collect and report clinical outcomes, including all device- or procedure-related adverse events, including but not limited to, infections, vasculitis, cellulitis, neuro-sensory and -motor events, device migrations, erosions, unplanned explantations, and re-implantation, to FDA through 5 years post-implantation on patients enrolled in G170301.

2. The Post-Approval Study of eCoin® for treatment of urgency urinary incontinence (UUI) is designed to collect effectiveness and safety data in a post-approval setting. This PAS is single-arm, prospective, multi-center study which will enroll 200 subjects with effectiveness determined at 12 months, with a secondary determination of effectiveness at 24 months. Safety and effectiveness data will be collected for 5 years post-implantation of study subjects. This will include assessment of the rate of device- or procedure- related adverse events (AEs) of interest, including but not limited to, infections, vasculitis, cellulitis, neuro-sensory and -motor events, device migrations, erosions, unplanned explantations, and re-implantation, over the course of 5 years.

   The performance goal for the primary effectiveness endpoint for this study is to demonstrate at least a 50% responder rate after 12 months of therapy. A responder is defined as a subject having ≥50% improvement of urgency urinary incontinence episodes as observed using a 3-day diary (72 hour diary).

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.