DE NOVO CLASSIFICATION REQUEST FOR vPATCH

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Non-implanted electrical stimulation device for management of premature ejaculation. A non-implanted electrical stimulation device for management of premature ejaculation is intended to be used in patients with premature ejaculation by delivery of electrical stimulation to the perineal muscles and nerves.

NEW REGULATION NUMBER: 21 CFR 876.5026

CLASSIFICATION: Class II

PRODUCT CODE: QRC

BACKGROUND

DEVICE NAME: vPatch

SUBMISSION NUMBER: DEN210012

DATE DE NOVO RECEIVED: March 30, 2021

SPONSOR INFORMATION:

Virility Medical
3521 Hatwynn Road
Charlotte, North Carolina 28269

INDICATIONS FOR USE

The vPatch is indicated as follows:

The vPatch is indicated for management of premature ejaculation in males who ejaculate after intromission. It is designed to increase the time between arousal and ejaculation by delivery of short duration, low-intensity electrical stimulation to the perineal muscles and nerves during intercourse.

LIMITATIONS

The sale, distribution and use of the device are restricted to prescription use in accordance with 21 CFR 801.109. Limitations on device use are provided in the Instructions for Use Manual:

Contraindications

Do not prescribe the vPatch if your patient:

- has been diagnosed with, or is receiving treatment for, pelvic cancer
- has an implanted electronic device (e.g., pacemaker, neurostimulator, etc.)
- suffers from perineal dermatological diseases, irritations, or lesions
- had surgery in the area of the genitals or anus
- requires any muscle rehabilitation in the area
- has diabetes with peripheral neuropathy

Warnings and Precautions

Instruct your patient:

- To contact you before using the device if he experiences any pain in the area
- Not to apply the vPatch to any area other than the male perineum
- That the vPatch is a single-user device and should not be transferred between users
- To stop stimulation and cease using the device if pain occurs in the pelvis
- To stop stimulation and cease using the device if allergic reaction occurs

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The vPatch is a single-use disposable patch designed to manage premature ejaculation. The vPatch contains electrodes that deliver electrical muscle stimulation (EMS) to the perineal muscles and nerves during intercourse to help the user postpone ejaculation. The patch works by delivering short duration, low intensity EMS to the target muscles and nerves. The stimulation contracts the pelvic floor muscles, which consequently, delays the rhythmic contractions of ejaculation. This increases the time between arousal and ejaculation. The vPatch is intended to be applied by the user to the perineum prior to intercourse and removed immediately after intercourse.

The vPatch is composed of the following components:

- Flexible Printed Circuit Board (f-PCB) with embedded software
- Adhesive electrodes (single channel)
- Batteries
- Foam housing
- Removable liner

Figure 1 is an image of the front and back of vPatch.

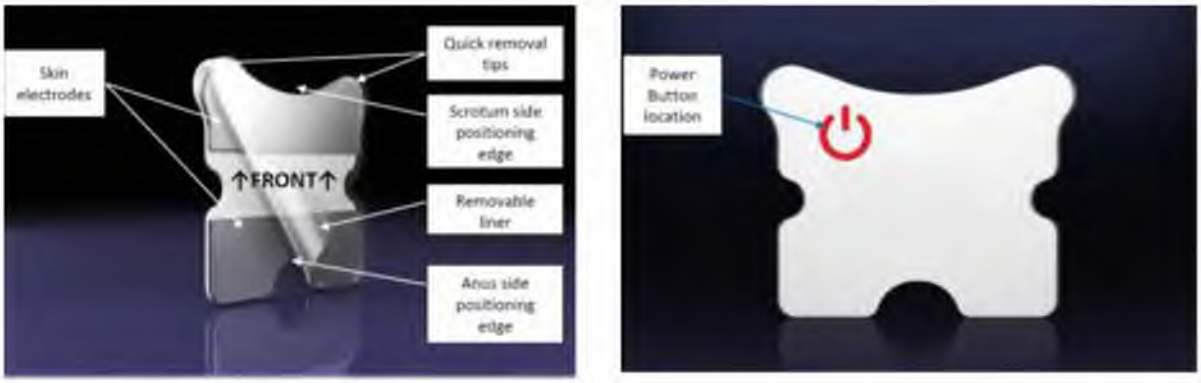

Figure 1 Front and back of vPatch

By pressing the activation button located on top of the device, the vPatch can deliver up to 15 minutes of stimulation at maximal intensity. The stimulation intensities of the vPatch are preconfigured and are labeled as Low and High, as shown below:

Intensity	**Label**
14.3 mA	High
9.9 mA	Low

vPatch Technological Specifications

Table 1 describes the key technological specifications of the vPatch.

Table 1: vPatch Technological Specifications		
Physical Measurements	Main Dimensions	Width 42 mm; Length 38 mm; Thickness 4.8 mm
	Electrode Contacting Area	Minimal size 475 mm^2
	Weight	Approximately 4 gr
Power Supply		LR721 Silver-oxide 2x 1.5VDC Non-rechargeable batteries
Number of Channels		1
Stimulation Current		HIGH Intensity: 14.3 mA ± 10% LOW Intensity: 9.9 mA ± 10%
Stimulation Voltage		HIGH voltage: 90 V ± 10% LOW voltage: 60 V ± 10%
Waveform		Symmetrical Biphasic Pulse
Pulse Duration		400 µs ± 10%
Frequency		30 Hz ± 10%
Electrodes		Hydrogel electrodes

Range of Impedance	1 kΩ – 6 kΩ ± 10%
Current Density	Exceeds 2 mA/cm^2
Ramp time	10 seconds
Interphase Interval	10 µs
Maximal Stimulation Duration	15 minutes

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

vPatch is categorized as a surface device in contact with intact skin for prolonged duration (>24 hours to 30 days, due to the likelihood of repeat use). The vPatch components that are in direct contact with intact skin in the perineum are the conductive hydrogel and foam medical tape.

The biocompatibility testing summarized below was performed in accordance with FDA's "Guidance Document titled Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,"" and demonstrated that the device is biocompatible for its intended use.

Endpoint	**Test Method**
Cytotoxicity	ISO Agarose Overlay ISO 10993-5 (2009)
Sensitization	ISO Closed Patch in Guinea Pigs ISO 10993-10 (2010)
Irritation	ISO Skin Irritation Study in Rabbits ISO 10993-10 (2010)

SHELF LIFE/STERILITY

vPatch is a non-sterile, single-use device.

The shelf-life for vPatch has been established at 2 years based on an accelerated aging study per ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

To support the 2-year shelf life, the sponsor conducted package integrity testing and functional testing. Package integrity testing consisted of the following:

- Visual inspection (per ASTM F1886/F1886M-16: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection)
- Dye penetration (per ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration)
- Bubble leak (ASTM F2096-11(2019), Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test))

- Seal strength (ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials)

The sponsor conducted functional testing after accelerated aging consisting of evaluation of stimulation parameters and shear testing as described in the Performance Testing – Bench section below.

The results demonstrate that vPatch has acceptable package integrity and functional performance over the duration of its 2-year shelf life.

ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

Electrical safety and electromagnetic compatibility testing were conducted on vPatch in accordance with the following standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 (Second Edition), 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 60601-2-10: 2012, AMD1: 2016, Particular requirements for the basic safety and essential performance of nerve and muscle stimulator
- IEC 60601-1-2: 2014, General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

vPatch passed electrical safety and electromagnetic compatibility testing consistent with the acceptance criteria outlined in these standards.

SOFTWARE

vPatch has a moderate level of concern (LOC), because a malfunction of the software could result in minor injury to the patient.

Software information corresponding to a moderate LOC as outlined in the FDA's guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005) was provided and is acceptable. The sponsor provided adequate documentation describing the software development program. In addition, the sponsor provided documentation that they performed a hazard analysis to characterize software risks, including device malfunction. The submission included verification and validation (V&V) testing to address the potential hazards with satisfactory results. Adequate documentation describing the software, firmware, software specifications, architecture design, software development environment, traceability, revision level history, and unresolved anomalies provides the foundation that the software will operate in a manner as described in the specifications.

PERFORMANCE TESTING - BENCH

vPatch underwent the following bench performance tests:

- Dimensional Validation Test: Demonstrated that critical measurements of vPatch are maintained and are consistent during production.

- Stimulation Parameters and Battery Performance Test: Verified vPatch can operate within its stimulation parameters during simulated use for its 15-minute use duration and ensured the battery life supports the 15-minute use duration.

- Shear Testing: Verified acceptable adhesion shear performance of vPatch in accordance with ASTM D6463 (2012), Standard Test Method for Time to Failure of Pressure Sensitive Articles Under Sustained Shear Loading.

The results of this testing demonstrate that vPatch performs as intended under anticipated conditions of use.

SUMMARY OF CLINICAL INFORMATION

USABILITY STUDY

Human factors (HF) validation testing was conducted following the FDA guidance document, *Applying Human Factors and Usability Engineering to Medical Devices*. (b)(4) male subjects between the ages of 18-60 participated in the study. Participants had access to vPatch and all accompanying labeling and documentation. Participants completed simulated use tasks with the vPatch and answered knowledge tasks (a total of (b)(4) critical tasks) to evaluate the usability of the entire user interface.

A total of (b)(4) use difficulties and (b)(4) user errors were observed for one task (turning off the device). There are no major safety implications from this finding. The patient labeling describes how to turn off the device textually and using images.

CLINICAL STUDY

The sponsor conducted a pivotal study "Evaluation of the safety and effectiveness of the vPatch device for the management and treatment of premature ejaculation."

The pivotal study was a multi-center, international, prospective, 2:1 randomized, double-blind, two-arm, sham-controlled, clinical investigation to evaluate the safety and effectiveness of vPatch.

The active device group was given fully functioning vPatch devices pre-configured to deliver stimulation intensity according to the subjective motor threshold intensity (electrical intensity

threshold for sensory and motor activation for increased perineal stimulation) reported by the patients during the initial clinical visit. The sham device group received vPatch devices pre-configured to deliver stimulation that is ineffective for muscle activation according to the patient's subjective sensory threshold. Except for the intensity level preconfigured in each arm, all devices (and packaging) were completely identical to ensure subjects and clinical staff could not distinguish between the active and sham devices.

The study objectives included the following:

- To assess the safety profile of the vPatch device and its effectiveness in delaying ejaculation when used in patients suffering from premature ejaculation.
- To assess the patient's perception of the ease of use of the vPatch device and treatment, through the use of a dedicated questionnaire.
- To assess the patient's perception of the changes in his Premature Ejaculation Profile (PEP) under different aspects with the use of device, through the use of a dedicated questionnaire (Control and Distress Domains of the Premature Ejaculation Profile (PEP) Questionnaire).
- To assess the patient's perceived intensity of orgasm by using the vPatch device, through the use of a validated tool (Orgasmometer).

All subjects gave written informed consent before any study assessment commenced. Screening included review of patient demographic and medical information, including age, previous medical history and disease etiology, risk factors, etc. All screened patients were subject to physical examination and selected according to eligibility criteria. Eligible subjects were randomized to their study arm and received the vPatch or the sham device (n=4 per subject), a notebook, an Orgasmometer, and a stopwatch to record the ejaculation time from erection. Prior to device or sham use, the subjects received training on the device at the clinical site. The patients were then asked to measure and record their baseline intravaginal ejaculatory latency time (IELT) using a stopwatch. The patients were also asked to measure their premature ejaculation profile (PEP) and orgasmic intensity (using an Orgasmometer) at baseline. The patients were expected to use the vPatch or the sham device four times over the course of the study. Following each use of vPatch or the sham device, IELT measurements, premature ejaculation profile (PEP) and orgasmic intensity were recorded. The patients filled out a safety questionnaire within 72 hours of each use. Subjects returned to the site for further follow-up assessment at the end of 12 weeks. During this visit, the patients underwent physical examination (height, weight, evaluation of the perineal area), measurement of vital signs (temperature, heart rate and blood pressure), and completed the Clinical Global Impression of Change (CGIC) questionnaire. Patients were also interviewed by the investigators, and the list of medications taken by the patients and all the adverse events experienced were reported.

Inclusion/Exclusion Criteria:

Inclusion	Exclusion
Male, age range 18-60	Patients with history of cardiovascular disorders

Patients who are diagnosed with clinical premature ejaculation or with self-perceived ELT < 3 minutes.	Patients with history of other sexual dysfunctions (other than premature ejaculation).
Patients with stable, heterosexual, monogamous, sexual relationship for at least 3 months at the time of the enrollment.	Patients suffering from erectile dysfunction.
Patients planning to maintain the relationship for the whole duration of the study.	Patients carrying any type of implanted pacemaker/defibrillator.
Patients with 75% of IELT baseline measurement < 2 minutes and 25% of IELT baseline measurement < 3 minutes at Visit 2.	Patients suffering from diagnosed Diabetes Mellitus with peripheral neuropathy.
Patients with Premature Ejaculation Diagnostic Tool (PEDT) measurement ≥ 11 at the time of enrollment.	Patients suffering from perineal dermatological diseases.
Patients with International Index of Erectile Function (IIEF-5) measurement ≥ 22 at the time of enrolment.	Patients suffering from perineal skin irritation / lesions.
Patients understanding the nature of the study and providing their informed consent to participation.	Patients suffering from any psychiatric major disease (axis 1) and/or taking any relevant medications.
Patients willing and able to attend the follow-up visits and procedures foreseen by study protocol.	Patients taking antidepressant therapy, topical anesthetic agents or sexual-related cognitive behavioral therapy within the 4 weeks before the enrollment.
	Patients with past occurrences of ejaculation before intromission.
	Patients with history of genital or anorectal neoplastic illness in the 2 years before the enrollment.
	Patients with pregnant partner.
	Patients who are participating or have participated in other clinical studies within the 30 days before the study enrollment.
	Patients with any medical incidence where the use of the device may jeopardize the patient's safety per Investigator's discretion.

Safety Endpoint:
The safety endpoint was the incidence and frequency of Adverse Events (AEs) in general and by seriousness, severity and relation to the study device.

Effectiveness Endpoints:
Two primary performance endpoints were defined as follows:

- The average change from baseline IELT is at least 50% higher in the active arm than in the sham arm.
- The proportion of subjects with improvement in clinical global impression of change (CGIC) in the active arm is at least 50% higher than in the sham arm.

The secondary performance endpoints defined include:

- Patient's subjective outcome assessment of the PEP from baseline to the end of the study.
- Evaluation of patient's subjective outcome assessment of orgasmic intensity via Orgasmometer from baseline to the end of the study.

Additional performance endpoints included:

- Proportion of subjects with any increase, 10%, 20%, 30%, 40%, and 50% increase from baseline in IELT.

Analysis sets

1. **Intent to Treat analysis set (ITT)**
   The ITT analysis set includes all subjects enrolled in the study. According to the ITT principle, all subjects will be analyzed in the group as assigned by randomization.
2. **Modified Intent to Treat analysis set (mITT)**
   The mITT analysis set consists of all subjects from the ITT analysis set who have received at least one study treatment during the home usage stage and who met the study eligibility criteria. In the mITT set, all subjects will be analyzed in the group as treated.
3. **Per-Protocol Analysis set (PP)**
   The PP analysis set will consist of all subjects from the mITT analysis set without major protocol violations.

The ITT analysis set served as the main analysis set for the efficacy and safety assessments. The primary and secondary efficacy assessments were also be performed on the mITT and the PP analysis sets as a sensitivity analysis.

Study Results:

Subject Disposition

A total of 70 male subjects were screened. 62 subjects were found eligible, and 59 subjects were randomized and enrolled in the study (ITT population). Seven subjects did not use the vPatch or sham device at all, and 1 subject in the sham arm used the sham device twice. Fifty-one subjects used the vPatch 3 or 4 times during the study. The 7 subjects did not use vPatch either due to reluctance or not being able to visit the clinic because of the official health rules due to the COVID-19 pandemic. The missing values were treated as failures or zero.

Tables 2 and 3 summarize the subject accountability and treatment allocation, respectively.

Table 2: Summary of accountability		
	N	**%**

Subjects Screened	70	100%
Subjects Eligible (% from screened)	62	88.57%
ITT Analysis Set (% from eligible)	59	95.16%
mITT Analysis Set (% from ITT)	52	88.14%
Subjects for Per Protocol Analysis Set	51	86.44%

Table 3: Treatment allocation

	Study Arm			
	Active		Sham	
	N	%	N	%
ITT Analysis Set	40	67.80%	19	32.20%
mITT Analysis Set	34	65.38%	18	34.62%
Subjects for Per Protocol Analysis Set	34	66.67%	17	33.33%

Study Demographics

Table 4 summarizes the study demographics. Except for height, most subject demographic characteristics were balanced between the two arms.

Table 4: Demographic characteristics for ITT Population

			Active	Sham	p-value
Age (years)		N	40	19	0.7989 (*)
		Mean (SD)	39.8 (9.28)	40.4 (9.69)	
		Median [min;max]	40.5 [21;56]	40.0 [26;54]	
Height (cm)		N	40	19	0.0519 (*)
		Mean (SD)	178.8 (5.94)	175.7 (4.74)	
		Median [min;max]	180.0 [165;190]	175.0 [168;187]	
Weight (kg)		N	40	19	0.4969 (*)
		Mean (SD)	81. 0 (13.7)	78.5 (10.78)	
		Median [min;max]	77.5 [56;120]	76.0 [64;110]	
BMI (kg/m^2)		N	40	19	0.9149 (*)
		Mean (SD)	25. 3 (3.86)	25.4 (3.15)	
		Median [min;max]	24.8 [16.5;35.1]	25.2 [22.1;35.9]	
Race	White	% (n/N)	100% (40/40)	100% (19/19)	1.0000 (#)

Note: p-values are unadjusted for multiple comparisons.

(*) t-test
(#) chi-square test

Safety Analysis:

Two AEs occurred in 2 sessions with the vPatch from a total of 186 sessions (52 training sessions, and 134 during the treatment period).

Therefore, the AE rate is 1.08% (2/186) in the active arm, versus 0% (0/70) in the sham arm, which is not a statistically significant difference.

The two AEs included discomfort due to device vibration in inguinal scar site and pain and discomfort during sexual intercourse in the pelvic area, and both were related to the study device. One of the AEs occurred during the stimulation intensity tuning phase, and the subject withdrew consent before using the vPatch during intercourse. Both AEs were considered mild and resolved upon cessation of use.

Effectiveness Analysis:

Primary effectiveness analyses

IELT is defined as the time from vaginal penetration to ejaculation. In this study, the patient's IELT was measured by their partner (using a stopwatch) during the home phase sessions of the clinical trials.

CGIC is defined as clinical global impression of change. The CGIC questionnaire was given to the patients to report their subjective sense of improvement with vPatch.

Table 5 summarizes the IELT and CGIC results for the ITT and mITT populations. The average improvement of IELT score over baseline among vPatch subjects was more than 50% greater than the average improvement among sham subjects in the ITT, mITT, and PP populations. For CGIC, the proportion of vPatch subjects experiencing an improvement was not 50% greater than the proportion among sham subjects in the ITT population; however, the 50% threshold was reached in the mITT and PP populations. Baseline IELT was 67.2 seconds in the vPatch arm and 62.1 seconds in the sham arm in the ITT population.

Table 5: IELT and CGIC: ITT, mITT, and PP Population

			n	Adjusted Means*	Standard Error	95% Confidence Intervals	p-values
Improvement of IELT over Baseline	**ITT**	**Active**	40	50.2 sec	8.37	[33.4; 67.0]	<0.0001
		Sham	19	16.9 sec	11.09	[-5.3; 39.2]	0.1335
		Difference (Active-Sham)	--	33.3 sec	11.94	[9.4; 57.2]	0.0073
	mITT	**Active**	34	55.5 sec	9.11	[37.2; 73.8]	<0.0001
		Sham	18	18.0 sec	11.78	[-5.7; 41.7]	0.1324
		Difference	--	37.5 sec	12.71	[11.9; 63.1]	0.0050

		(Active-Sham)					
	PP	**Active**	34	55.3 sec	9.23	[36.7; 73.9]	<0.0001
		Sham	17	17.0 sec	12.09	[-7.3; 41.4]	0.1653
		Difference (Active-Sham)	--	38.2 sec	12.88	[12.3; 64.2]	0.0047
			n	**%**		**95% Confidence Intervals**	**p-values**
Patients Experiencing any Improvement in CGIC	**ITT**	**Active**	25	62.5		[45.8; 77.27]	0.1477
		Sham	8	42.11		[20.25; 66.50]	
	mITT	**Active**	25	73.53		[55.64; 87.12]	0.0371
		Sham	8	44.44		[21.53; 69.24]	
	PP	**Active**	24	73.53		[55.64; 87.12]	0.0274
		Sham	7	41.18		[18.44; 67.08]	

*Means were adjusted for baseline values, age, and center.

Secondary effectiveness analyses

The secondary effectiveness endpoints did not have pre-specified success criteria; only the PP population was evaluated.

PEP: PEP stands for premature ejaculation profile. PEP is measured through the use of a questionnaire. The questionnaire assesses the patient's perception of changes in PEP under different aspects with the use of vPatch. The vPatch patients had higher PEP scores compared to the sham patients.

Table 6: Premature Ejaculation Profile (PEP): Per Protocol Population, Improvements over Baseline

		Adjusted Mean*	Standard Error
Perceived control over ejaculation	Active	1.2	0.18
	Sham	0.3	0.25
	Difference (Active-Sham)	0.9	0.29
Satisfaction with sexual intercourse	Active	0.9	0.20
	Sham	0.4	0.26

	Difference (Active-Sham)	0.5	0.33
Personal distress related to ejaculation	Active	1.1	0.20
	Sham	0.4	0.28
	Difference (Active-Sham)	0.7	0.33
Interpersonal difficulty related to ejaculation	Active	1.5	0.21
	Sham	0.5	0.31
	Difference (Active-Sham)	0.9	0.36

*Means were adjusted for baseline values, age, and center.

Orgasmic Intensity: A patient's orgasmic intensity is measured using an Orgasmometer. An Orgasmometer is a validated tool to quantitively measure the intensity of orgasmic pleasure. This endpoint evaluates the patient's subjective outcome assessment of orgasmic intensity from baseline to the end of the study. The vPatch patients had higher orgasmic intensity scores compared to the sham patients.

Table 7: Orgasmic Intensity: Per Protocol Population, Improvements over Baseline		
	Adjusted Mean*	Standard Error
Active	0.3	0.37
Sham	-0.6	0.53
Difference (Active-Sham)	0.8	0.62

* Means were adjusted for baseline values, age, and center.

Additional performance analysis

Table 8 represents the data from the additional endpoint indicating the number and proportion of subjects with improvement in IELT from baseline. At each percentage level, a greater proportion of vPatch patients experienced improvement compared to the sham arm.

Table 8: Improvement in IELT from baseline – Per Protocol Population				
	Active		**Sham**	
	N	**%**	**N**	**%**
Any Improvement	31	91.18%	9	52.94%
Improvement by at least 10%	30	88.24%	8	47.06%
Improvement by at least 20%	27	79.41%	7	41.18%
Improvement by at least 30%	22	64.71%	6	35.29%
Improvement by at least 40%	21	61.76%	5	29.41%
Improvement by at least 50%	19	55.88%	4	23.53%

Pediatric Extrapolation

For medical devices, the Federal Food, Drug, and Cosmetic Act defines pediatric patients as persons before their 22nd birthday. Because few patients were evaluated within the age range of 18-21, it was unclear whether there were enough data to support effectiveness in this population. However, patients aged 18 to 21 do not carry additional differences or risks relative to the adult patient population studied, and this device has a likely benefit for this group.

LABELING

The vPatch labeling consists of the package label (high and low intensity), patient labeling, and physician labeling. The labeling documents are consistent with the clinical data and covers all the hazards and other clinically relevant information that may impact use of the device. The labeling is sufficient and satisfies the requirement of 21 CFR 801.109 for prescription devices. Both the physician and patient labeling include the indications for use, device description, contraindications, warnings, precautions, summary of the clinical study, and instructions for use.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the non-implanted electrical stimulation device for management of premature ejaculation:

Identified Risks to Health	Mitigation Measures
Use error leading to patient pain, discomfort, or injury	Labeling
Electrical, mechanical or thermal fault, system malfunction, or other device failure resulting in lack of treatment or patient discomfort/injury (e.g., electrical shock, burn, tissue damage, or interference from other medical devices or electrical equipment)	Non-clinical performance testing Electrical safety testing Electromagnetic compatibility testing Software validation, verification, and hazard analysis Shelf-life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling

SPECIAL CONTROLS

In combination with general controls of the Food Drug & Cosmetic Act, the non-implanted electrical stimulation device for management of premature ejaculation is subject to the following special controls:

(1) The device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Mechanical performance;
   (ii) Electrical stimulation parameters; and
   (iii) Battery performance.

(4) Performance testing must support shelf life by demonstrating continued device functionality over the identified shelf life.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include:
   (i) Specific instructions regarding safe placement and correct use of the device;
   (ii) Warning(s) against use by patients with active implanted medical devices; and
   (iii) A shelf life.

BENEFIT-RISK DETERMINATION

The benefits and risks of the device are based on data collected in the pivotal clinical study described above.

Regarding the probable risks, 2 AEs were reported in the pivotal study, both of which related to discomfort (1 subject reported pain in an inguinal scar and the other subject reported pelvic discomfort during to intercourse). Both AEs were mild and resolved after cessation of device usage.

Regarding the probable benefits, in the pivotal study, there was a mean improvement in IELT of (b)(4) in the vPatch arm versus (b)(4) n the sham arm (a factor of (b)(4)). Also, the CGIC was higher in the treatment arm versus the sham arm.

PATIENT PERSPECTIVES

The pivotal clinical study used the following validated Patient Reported Outcome (PROs):

- Clinical Global Impression of Change (CGIC): This questionnaire was used to assess the primary endpoint. This questionnaire captured the proportion of patients that reported an improvement from baseline when using vPatch.

- Premature Ejaculation Profile (PEP): This questionnaire was used to assess a secondary endpoint. This questionnaire captured perceived control over ejaculation, satisfaction

with sexual intercourse, personal distress related to ejaculation and interpersonal difficulty related to ejaculation.

Based on the CGIC questionnaires, a greater proportion of the subjects who used vPatch experienced improvement compared to patients the sham arm. The subjects who used vPatch reported a higher average PEP score compared to the sham arm.

The patient perspectives from this study are favorable for the vPatch.

BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

> The vPatch is indicated for management of premature ejaculation in males who ejaculate after intromission. It is designed to increase the time between arousal and ejaculation by delivery of short duration, low-intensity electrical stimulation to the perineal muscles and nerves during intercourse.

The probable benefits outweigh the probable risks for the vPatch. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the vPatch is granted and the device is classified as follows:

> Product Code: QRC
> Device Type: Non-implanted electrical stimulation device for management of premature ejaculation
> Regulation Number: 21 CFR 876.5026
> Class: II