

**DE NOVO CLASSIFICATION REQUEST FOR
PROLONG**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Vibrator for climax control of premature ejaculation. A vibrator for climax control of premature ejaculation is used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

NEW REGULATION NUMBER: 21 CFR 876.5025

CLASSIFICATION: II

PRODUCT CODE: PIA

BACKGROUND

DEVICE NAME: PROLONG™

SUBMISSION NUMBER: DEN130047

DATE OF DE NOVO: NOVEMBER 21, 2013

CONTACT: ERGON MEDICAL LTD.
C/O BARRY PEARCE, SHOTWELL & CARR, INC.
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REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS II

INDICATIONS FOR USE

Prolong is used as part of a climax control program for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation through the use of the training sessions using the stimulating vibratory effects of the device on the penis as part of the "start-stop" technique. Prolong is intended to be available as an over-the-counter device.

LIMITATIONS

Limitations on device use are also achieved through the following statements included in the Instructions for Use Manual:

Warnings:

If you suffer psychological problems or physical symptoms other than early ejaculation such as passing a lot of urine, you must consult your doctor. Excessive use will not necessarily give better results and can injure your skin. Do not use on inflamed or broken skin. Not for internal use. Do not swallow. Keep out of sight and reach of children. Intended for personal use only. Do not share. Use only the lubricant supplied with device. Do not use device close to sensitive equipment which may be affected by electromagnetic interference. No serviceable parts. Store in a cool, dry place.

Do not use for more than 30 minutes at a time and no more than 3 times per week.

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

DEVICE DESCRIPTION

The PROLONG™ device consists of the PROLONG™ vibrating device and a 4-ounce bottle of water-based lubricant. The lubricant was FDA cleared under K013086. The PROLONG™ vibrating device includes a white silicone body and a vibrator unit as shown in Figure 1. The vibrator unit comprises a 3-Volt coin (pancake) motor connected to a battery pack of two battery cells (Type PX625A) shrink wrapped together and an Acrylonitrile Butadiene Styrene (ABS) slide switch unit to activate the motor. The device should be disposed of at the end of the six week treatment.

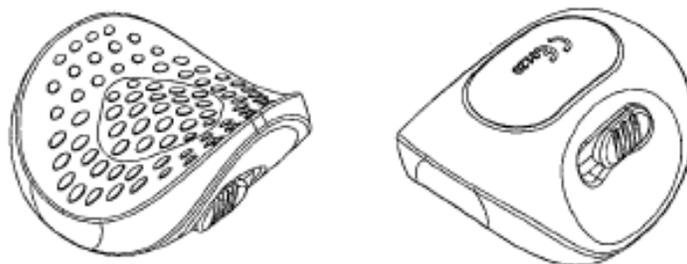


Figure 1: PROLONG™ Vibrating Device

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The patient-contacting materials of the PROLONG™ device are silicon rubber and Acrylonitrile Butadiene Styrene (ABS). Samples of the final finished device were subjected to cytotoxicity, sensitization and irritation testing according to ISO 10993-5 for cytotoxicity and ISO 10993-10 for irritation and skin sensitization. The extracts were determined to be non-cytotoxic, non-sensitized and produced a negligible irritation response.

SHELF LIFE/STERILITY

Prolong is a non-sterile, reusable and single-user device. It is intended only for external use and the instructions for use include appropriate cleaning instructions for the Prolong device. The accompanying FDA-cleared lubricant (K013086) has a two-year shelf life. The sponsor performed battery testing to demonstrate that the shelf life of the battery is 3 years.

ELECTROMAGNETIC COMPATIBILITY (EMC) AND ELECTRICAL SAFETY

Testing of the battery and motor against the requirements of IEC 60601-1, EN 60601-1-2, 55014-1, 61000-4-2, 61000-4-3, 61000-6-1, 61000-6-3 and 61000-4-8 was performed. The results of the testing confirmed that the device complies with all applicable parts of the EMC standards. Testing to EU standards for EMC was determined to be sufficient to also satisfy the requirements in the FDA-recognized IEC versions of the standards. Electrical and thermal safety testing was conducted in accordance with standard ANSI/AAMI ES60601-1. All measurements and test results were within the acceptable limits specified by the safety standard.

PERFORMANCE TESTING – BENCH

Mechanical Safety – Pull testing and mechanical durability testing were conducted to demonstrate that the device will withstand forces encountered during use.

Battery Testing - The durability test was conducted to demonstrate the battery capacity to sustain a minimum of six-week use of the subject devices nearing or at the end of their three-year shelf life. The test units were subject to battery tests that were conducted over a 6-week period with the devices being switched on and off. The devices performed satisfactorily and met the criteria for use as recommended in the instructions for use.

SUMMARY OF CLINICAL INFORMATION

A single site, open-label clinical audit/evaluation of Prolong was conducted to evaluate the safety and effectiveness of the device in subjects with premature ejaculation. The study used the Prolong together with an FDA-cleared lubricant manufactured by Trigg Laboratories, Inc., California, or the CE Marked (but not FDA cleared) Prolong lubricant manufactured by Megasol Cosmetic GmbH, Föhren, Germany. The Megasol lubricant is currently supplied with the Prolong in Europe. Only the Trigg lubricant will be supplied with the Prolong in the US. Subjects were allocated openly in an alternate sequential manner to receive either the Trigg lubricant or the Prolong lubricant. The Prolong was used in conjunction with the lubricant at least three times per week for a total of six weeks.

A total of 39 subjects were screened of which 33 were enrolled in the study. Of the 16 subjects who received Prolong lubricant, 10 subjects completed the six week treatment period with follow-up at every time point; of the 16 subjects who received Trigg water-based lubricant, 12 subjects completed the six week treatment period with follow-up at every time point.

Study Objectives:

- To measure and assess the improvement in performance in terms of ejaculation time during the intra-vaginal ejaculatory latency time (ILET) or masturbation following six weeks of treatment with the Prolong and lubricant;
- To assess the reduction in distress in subjects with premature ejaculation following treatment;
- To assess the improvement of parameters of sexual satisfaction following treatment;
- To assess adverse side effects during use of the Prolong and lubricant, if used as instructed.

After an initial screening, visits involved completion of several questionnaires such as Golombok Rust Inventory of Sexual Satisfaction (GRISS), Beck Anxiety Inventory (BAI), and Beck Depression Inventory (BDI-II).

Physical examination included vital signs and blood hematology, such as complete blood count and biochemistry screen, including random blood glucose, thyroid and liver function tests, and urine screening for drugs of abuse, including alcohol. Eligible subjects with written informed consent received the Prolong, lubricant, demonstration video, stop-watch, and a six-week diary card to record ejaculation time from erection.

Subjects returned for further follow-up assessment at the end of the six-week treatment, when they were again asked to complete the questionnaires and a 10-point Likert satisfaction scale. Their diary cards recorded all individual times to ejaculation from erection during intercourse or masturbation and any side/adverse effects, if any occurred, for each of the six weeks of treatment.

Inclusion/Exclusion Criteria:

Inclusion	Exclusion
Male subject ≥ 18 and ≤ 60 years of age	Organic cause ED (substance misuse, pelvic trauma/surgery)
Patients with a Diagnostic and Statistical Manual of Mental Disorders, 4th Ed., Text Revision (DSM-IV-TR) criteria for premature ejaculation	Diabetes
Subjects willing and able to provide written informed consent to participate in the treatment audit/evaluation	Prostatitis
Subjects able to attend follow-up	Abnormal screening blood test
	Active substance misuse
	Patient meets BDI-II for depression

Outcome Measures:

- Comparison of pre-and post-treatment scores in measurements of BDI, BAI, and GRISS at end of treatment (week 6)

- Change in latency period to ejaculation on a weekly basis using stop-watch measurement of IELT or during masturbation
- Drop-out rates
- Subjective satisfaction with treatment on a 10-point Likert scale.

Statistical Methods:

The data were evaluated using descriptive statistics including mean, median, 95% confidence interval (CI) and change from pre-treatment (baseline) to end of treatment for both treatment groups. No formal statistical comparison between treatment groups was planned or conducted.

Results:

Thirty-three subjects were enrolled in the study and 23 were still using the device at week 6 with a median increase in time to ejaculation for these 23 subjects of 3 minutes.

A comparison of pre-treatment and end-of-treatment scores for completed BAI, BDI-II and GRISS questionnaires showed an overall improvement in both treatment groups for distress such as anxiety, depression, and parameters of sexual satisfaction such as sexual function and sexual relationship, respectively, at the end of the study. Six-week use of the Prolong with lubricant was associated with an improvement in impotence, premature ejaculation, avoidance, dissatisfaction, and infrequency in both treatment groups.

There were no reported (0%) adverse events (AEs) for the Prolong hand-held device in either of the two lubricant subject groups who completed the six week treatment period. Eleven subjects dropped out of the study; none were related to treatment side effect/adverse events. A 10-point Likert satisfaction survey showed high levels of satisfaction with use of the Prolong and lubricants.

Clinical Conclusions:

- No adverse events occurred when either the Trigg water-based lubricant or Prolong lubricant were used with the Prolong.
- Trigg water-based and Prolong lubricants, when used with the Prolong for a minimum of three times per week for six weeks, were effective in the treatment of premature ejaculation. There were 33 subjects enrolled in the study and 23 were still using the device at week 6 with a median increase in time to ejaculation for these 23 subjects of 3 minutes.
- A 10-point Likert satisfaction survey of all subjects who responded to treatment showed high levels of satisfaction with ease of use and effectiveness of the Prolong and lubricants.

Comparison with Cognitive Behavioral Therapy (CBT):

The start-stop and squeeze techniques incorporated with Cognitive Behavioral Therapy (CBT) are the gold standard training program for the treatment of premature ejaculation, consisting of using a device such as a desensitizing ring daily for no more than 30 minutes for up to six weeks. A study by Zamar (2012) using Prolong in 58 subjects was found to delay time to ejaculation from 48 seconds (0.8 minutes) to 8 minutes and 48 seconds (8.8 minutes) on average in 61% of men, compared to 2 minutes and 36 seconds (2.6 minutes) in 40% of men having the CBT with a difference on average of 6 minutes and 12 seconds (6.2 minutes) between the two groups.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of vibrator for climax control of premature ejaculation and the measures necessary to mitigate these risks.

Identified Risk	Mitigation Measure
Pain or discomfort due to misuse of device	Labeling
Burns	Electrical and Thermal Safety Testing Labeling
Electrical Shock	Electrical Safety Testing Labeling
Adverse skin reactions	Biocompatibility Testing
Patient injury due to device breakage or failure	Mechanical Safety Testing Labeling
Interference with other devices/electrical equipment	Electromagnetic Compatibility Testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the Food Drug & Cosmetic Act, the Vibrator for Climax Control of Premature Ejaculation is subject to the following special controls:

- (1) The labeling must include specific instructions regarding the proper placement and use of the device.
- (2) The portions of the device that contact the patient must be demonstrated to be biocompatible.
- (3) Appropriate analysis/testing must demonstrate electromagnetic compatibility (EMC) safety, electrical safety, and thermal safety of the device.
- (4) Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

BENEFIT/RISK DETERMINATION

Probable benefits were demonstrated in two studies presented by the sponsor.

Prolong Device (Two Lubricants Tested)

- Six-week use of the Prolong device with lubricant was associated with an improvement in impotence, premature ejaculation, avoidance, dissatisfaction, infrequency in both treatment groups. The study results showed that 33 subjects were enrolled in the study and 23 were still using the device at week 6 with a median increase in time to ejaculation for these 23 subjects of 3 minutes. The subjects were followed up to six months post treatment and found to have stable or further improved delayed times to ejaculation.

Prolong Device versus Cognitive Behavioral Therapy (CBT) Study

- The device showed the delay of time to ejaculation from 48 seconds (0.8 minutes) to 8 minutes and 48 seconds (8.8 minutes) on average in 61% of men, compared to 2 minutes and 36 seconds (2.6 minutes) in 40% of men having the CBT with an average difference of 6 minutes and 12 seconds (6.2 minutes) between the two groups.

The risks of the Prolong device are based on nonclinical laboratory data as well as data collected in the clinical study described above. No side effects were reported during the six-week treatment period.

In conclusion, given the available information above, the data provides support for a climax control program using the Prolong device for males who suffer from premature ejaculation, where the probable benefits outweigh the probable risks for the Prolong. The device provides some benefit and the risks can be mitigated by the use of general and the identified special controls.

CONCLUSION

The *de novo* for the Prolong™ is granted and the device is classified under the following:

Product Code: PIA

Device Type: Vibrator for climax control of premature ejaculation

Class: Class II

Regulation: 21 CFR 876.5025