DE NOVO CLASSIFICATION REQUEST FOR EROXON

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Non-medicated topical formulation for treatment of erectile dysfunction. A non-medicated topical formulation for treatment of erectile dysfunction is a device that is applied on the penis and stimulates the nerve endings by inducing a temperature change, leading to tumescence and erection.

NEW REGULATION NUMBER: 21 CFR 876.5021

CLASSIFICATION: Class II

PRODUCT CODE: QWW

BACKGROUND

DEVICE NAME: Eroxon

SUBMISSION NUMBER: DEN220078

DATE DE NOVO RECEIVED: October 21, 2022

SPONSOR INFORMATION:

Future Medical Developments Limited
10 Holmes Court,
Morristown, NJ 07960

INDICATIONS FOR USE

The Eroxon is indicated as follows:

Treatment of erectile dysfunction in adult males aged 22 years and over.

LIMITATIONS

Contraindications

- Do not use the Eroxon if allergic to any of the product ingredients.

Warnings

- Stop using the Eroxon if any irritation (e.g., burning, itching or redness) is observed from the use. If irritation continues, seek medical attention.

Precautions

- The product should not be used by anyone under the age of 22.
- This product should not be used if there is any disease or deformity of the penis.
- Do not use the product if the skin on the penis is red or sore or appears damaged or broken.
- Do not use the product if advised by the doctor to avoid sexual activity.

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

DEVICE DESCRIPTION

Eroxon is a non-medicated, hydro-alcoholic gel formulation for topical application to the glans penis prior to sexual intercourse. Eroxon is intended as a topical treatment for male erectile dysfunction, which is the inability to achieve or maintain an erection sufficient for satisfactory sexual performance.

Upon application, Eroxon stimulates blood flow through the penis. The volatile components of the formulation (alcohol, water) evaporate to create a rapid, localized cooling effect on the glans penis followed by a recovering slower warming effect. This stimulates nerve endings leading to tumescence and erection.

Eroxon is supplied in single-dose aluminum tubes. Each tube is designed to dispense approximately 300 mg of gel.

The device is supplied non-sterile and is for single use only.

The device formulation for Eroxon and information on the ingredients in its formulation are provided in the **Table 1**:

Table 1: Device formulation and ingredient information

Ingredient	Description	Quantity (%w/w)	Chemical Grade	Supplier Name	Chemical Abstract Service (CAS) Number
Alcohol	Volatile compound	(b)(4)	USP	Berkel AHK	64-17-5
Purified Water	Volatile compound		USP	In house ring main system	7732-18-5

Ingredient	Description	Quantity (%w/w)	Chemical Grade	Supplier Name	Chemical Abstract Service (CAS) Number
Glycerin	Non-volatile compound	(b)(4)	USP	Cremer Oleo GmbH & Co. KG	56-81-5
Propylene glycol	Non-volatile compound		USP	Hedinger GmbH & Co. KG	57-55-6
Carbomer (Carbopol Ultrez 10)	Viscosity modifier		NF	Lubrizol Advanced Materials, Inc. Europe B.V.B.A	195739-91-4
Potassium hydroxide	pH modifier		NF	Merck KGaA	1310-58-3

The specifications for Eroxon are provided in **Table 2.**

Test	Specification	Method
Appearance	Clear to turbid, colorless to off-white gel, free from particulate matter	Visual
Odor	Alcoholic odor	Organoleptic
Alcohol content (%)	(b)(4)	GC in-house method (GB1-QA-PT-330)
pH		USP <791>
Viscosity (cP)		USP <912>
Minimum Fill	Conforms to USP	USP <755>
Osmolality (mOsm/kg)	(b)(4)	USP <785>
Microbial Quality		USP <61> <62>
Antimicrobial Effectiveness	Conforms to USP 51 for category 2 products	USP <51>
USP – United States Pharmacopeia TAMC – Total aerobic microbial count TYMC – Total yeasts/mold count GC – Gas Chromatography		

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

Eroxon is categorized as a surface device that contacts both the skin and mucosal membrane for a limited (<24 hour) contact duration with the potential for repeat exposure.

The following biocompatibility endpoints were assessed in accordance with the 2020 FDA guidance document, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing":

Endpoint	Test Method
Cytotoxicity	MEM Elution Test ISO 10993-5:2009
Sensitization	Guinea Pig Maximization ISO 10993-10:2010
Irritation	Dermal Irritation Test in Rabbits ISO 10993-23:2021
Acute Systemic Toxicity	Acute Systemic Toxicity Study in Rats ISO 10993-11: 2017

The results demonstrate that Eroxon is biocompatible.

In addition, the sponsor completed an extractables/leachables study that evaluated the chemicals that may leach out from the primary packaging and enter Eroxon over the course of long-term storage. The study evaluated extractables from the primary packaging (aluminum tube) and also compared the aged Eroxon formulation in aluminum tube and non-aged Eroxon formulation in an aluminum tube. This study did not identify extractables from the primary packaging materials that would leach out at levels above the reporting limit and contaminate Eroxon during storage.

SHELF-LIFE/STERILITY

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

The shelf-life for Eroxon has been established at 12-months based on real-time aging studies at 25°C and 30°C.

To support the 12-months shelf-life, the sponsor conducted appearance, odor, alcohol content percentage, pH (USP<791>), viscosity (USP<912>), minimum fill (USP<755>), osmolality (USP <785>), microbial quality (USP<61><62>), antimicrobial effectiveness (USP <51>) and weight change % on the samples. Following exposure to the real-time aging conditions, Eroxon met the acceptance criteria for each of the tests as described in **Table 2**. The results demonstrate that Eroxon has acceptable stability and functional performance over the duration of the 12-month shelf life.

PERFORMANCE TESTING - BENCH

Eroxon underwent the following bench performance tests:

- Condom Compatibility test: Demonstrated that the tensile or airburst properties of natural rubber latex, polyurethane and polyisoprene condom are not significantly affected by Eroxon in accordance with ASTMD7661-10. This testing supports the statement in the device labeling that Eroxon is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

- Device specification testing: Demonstrated that Eroxon can meet its specifications as described in **Table 2.**

- Temperature profiling test: Demonstrated that Eroxon can create a rapid cooling effect followed by a recovery warming effect under ex-vivo simulated use conditions.

The results of this testing demonstrate that Eroxon 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*. The sponsor conducted a single-visit, single-site study with 32 users initially enrolled and 21 users completing the human factors portion of the study to evaluate if users were able to properly self-diagnose erectile dysfunction (ED), make a correct self-selection decision based on the device labeling, and correctly perform performance-based and knowledge-based tasks (based on the device labeling and instructions for use) necessary for the safe and effective use of the device in the absence of medical supervision.

Overall, nearly all users (97%) were able to correctly self-diagnose their ED. The single user who incorrectly self-diagnosed was judged by the sponsor as likely to have previous or episodic (not current) experience of ED. The study concluded that the likelihood of a user incorrectly self-diagnosing as an ED sufferer was inherently low. Evaluation of the performance and knowledge-based tasks demonstrated that the risks associated with the use of Eroxon were reduced to an acceptable level. The results of this study supported that the labeling is acceptable for over-the-counter use.

CLINICAL STUDY

The sponsor conducted a pivotal study to support the safety and effectiveness of Eroxon for the treatment of erectile dysfunction.

The pivotal study was a multi-center, international, 2:1 randomized, open-label, home use, parallel group clinical investigation. The study was conducted over a period of 24-weeks.

The patients were randomized into one of two treatment groups, the investigational group with application of Eroxon or the control group with oral intake of tadalafil 5mg tablets. (The use of tadalafil in the pivotal study was exploratory and was not used for safety and effectiveness comparison against Eroxon). Each patient could participate in the study for up to 9 study site visits within 30 weeks: up to 5 weeks of screening, 24 weeks of treatment, and 1 week of follow-up. The 24 weeks of treatment period was divided into six 4-week periods. The patients completed onset of action questions after the first intercourse attempt following each treatment and the International Index for Erectile Function (IIEF) and self-esteem and relationship questionnaire (SEAR) at the end each 4-week period. Patients and their female partners were monitored for adverse events through self-reported diaries for each 4-week use period and, monitoring symptoms as they experienced them.

The inclusion and exclusion criteria for the study are as follows:

Inclusion Criteria

1. Males aged 22-70.
2. Confirmed clinical diagnosis of ED for more than 3 months.
3. Answered 'yes' to the question regarding the presence of residual Erectile Function (EF) over the past 3 months.
4. Had been involved in a continuous heterosexual relationship at least 6 months prior to screening.
5. Had documented written informed consent from both patient and his female partner.
6. If the male patient's female partner was of childbearing potential from the time of first sexual intercourse attempt during the screening period until the last administration of investigational treatment, then the couple must have used a medically acceptable form of contraception for at least 3 months prior to entering the clinical investigation and agreed to continue such use for at least 1 month after the last administration of Eroxon or tadalafil (5 mg). Patients who were or wished to become pregnant were not included in the investigation.
7. Patient and his female partner were capable of understanding and complying with the requirements of the clinical investigation plan and signed the informed consent form (ICF) prior to participation in any investigation-related procedures.
8. Had Low International Index for Erectile Function- Erectile Function (IIEF-EF) scores ($\leq$25) at the end of the screening period (i.e., Visit 2).

Exclusion Criteria

1. Had any significant or serious cardiovascular, pulmonary, hepatic, renal, gastrointestinal, hematological, endocrinological, metabolic, neurological or psychiatric disease.
2. Had any history of an unstable medical or psychiatric condition or used any medication that, in the opinion of the Investigator, was likely to affect the patient's ability to complete the investigation or precluded the patient's participation in the investigation.
3. Had any presence of a symptomatic, active urinary tract infection diagnosed by the Investigator or their delegate at screening or during the investigation.

4. Had a chronic indwelling urethral catheterization or penile anatomical abnormalities (e.g., penile fibrosis) that would significantly impair EF.
5. Had a history of operations for Peyronie's disease.
6. Had primary hypoactive sexual desire or any history of hypogonadism.
7. Had a history of radical prostatectomy.
8. Had a history of severe/uncontrolled diabetes.
9. Were taking 2 or mor anti-hypertensives for the treatment of blood pressure.
10. Had a hypersensitivity to any of the excipients.
11. Had concomitant treatment with sildenafil citrate, vardenafil, and other PDE-5 inhibitors.
12. Were taking alpha blockers, guanylate cyclase stimulators, such as riociguat, doxazocin, or any form of organic nitrate.
13. Were receiving testosterone pellets.
14. Had any penile surgery except circumcision.
15. Had any treatment with acetyl cysteine within 6 months.
16. Had any treatment with dihydroergotamine within 6 months.
17. Had loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy
18. Had increased intracranial pressure (e.g., head trauma or cerebral haemorrhage) or inadequate cerebral circulation.
19. Had a history of migraine or recurrent headache.
20. Had aortic or mitral stenosis.
21. Had hypertrophic obstructive cardiomyopathy.
22. Had constrictive pericarditis or pericardial tamponade.
23. Had closed-angle glaucoma.
24. Had a nursing partner, a partner who was pregnant, or a partner who wished to become pregnant during the course of the investigation.
25. Had confirmed positive results from urine drug screen (amphetamines, benzodiazepines, cocaine, cannabinoids, opiates, barbiturates, tricyclic antidepressants and methadone) or from the alcohol breath test at screening (for clarification, any positive result from the urine drug screen or alcohol breath tests at screening. If a patient was using medication which may have given a positive result, exclusion was at the PI's discretion.
26. Had recent (in the last 12 months) clinical evidence of alcoholism or drug abuse.
27. Had a positive screen for hepatitis B consisting of hepatitis B surface antigen hepatitis C antibody and human immunodeficiency virus.
28. Had any clinically significant abnormal laboratory value, vital signs, or other safety findings as determined by medical history, physical examination, or other evaluations conducted at screening or on admission.
29. Were unwilling to cease use of vacuum devices, intracavernosal injections, PDE-5s, or other non-clinical investigation therapies for ED for the entire course of the investigation.
30. Patient or their partner were unwilling to agree to make the required attempts at sexual intercourse during the treatment period.
31. Had a history of unresponsiveness to PDE-5 treatment or significant side effects, exclusion visual disturbances, with PDE-5s.
32. Had fewer than 4 attempts at sexual intercourse during the screening period.
33. Patient or their partner were illiterate or were unable to understand the language in which the questionnaires are available.

34. Had received an investigational product during the 90 days prior to dosing for this investigation.
35. Patient or his partner could not communicate reliably with the Investigator.
36. Has severe premature ejaculation (little or no control of ejaculation at the time of penetration).

Study Endpoints

The co-primary effectiveness endpoints for the study were:

(1) Improvement compared to baseline of the erectile function (EF) domain of the International Index for Erectile Function (IIEF) in patients randomized to Eroxon, at 24 weeks post-randomization (mean change from baseline greater than zero).
(2) Mean change from baseline of the IIEF-EF in patients randomized to Eroxon, at 24 weeks post-randomization, greater than or equal to the minimally clinically important difference (MCID) of 4, as published by Rosen et al 2011.

The secondary effectiveness endpoints of the study were:

(1) Mean percentage of Eroxon uses per patient that result in the patient noticing their erection starting within a certain period of time was greater than 30% during the 24-week treatment period.
(2) Mean percentage of Eroxon uses per patient that result in the ability to have penetrative sex within a certain period of time was greater than 30% during the 24-week treatment period.

The study also had several exploratory endpoints. However, the only exploratory endpoint considered by FDA to support this De Novo submission was:

(1) Proportion of patients reporting a meaningful improvement in the IIEF-EF domain according to the criteria published by Rosen et al 2011, assessed every 4-weeks post-randomization (evaluated by mild, moderate, and severe ED).

The effectiveness endpoints were not evaluated in comparison to the control group.

Safety Endpoints

Safety was evaluated based on treatment emergent adverse events (TEAEs) and standard physical and laboratory assessments. A TEAE was defined as any adverse event that had its onset date on or after the date of randomization and up to 7 days after treatment discontinuation.

Analysis Population

The primary analysis population for evaluation of effectiveness was the full analysis set, which included all randomized patients. The primary safety analysis was performed on the safety analysis set, which included all randomized patients who used Eroxon or the control medication at least once.
In the case of randomization/treatment errors, patients were analyzed according to their initially received treatment.

Study Results

While information regarding the tadalafil control is provided in this section, data from the control group is not used for comparison of safety and effectiveness against Eroxon.

Participant Disposition
The study randomized a total of 96 patients in countries of Georgia (n=30), Poland (n=54), Bulgaria (n=3), and the US (n=9). A total of 48 patients were randomized to Eroxon arm and the other 48 patients were randomized to the tadalafil 5 mg arm. The randomized patients made up the full analysis set for efficacy analyses. Of the randomized patients, 94 received treatment and were included in the safety analysis set for safety analyses. The two remaining patients withdrew consent prior to using the treatment and therefore did not complete the study.

Seven patients, 6 in the Eroxon group and 1 in the tadalafil group, withdrew from treatment. Lack of effectiveness was cited as the reason why 3 of the 6 patients in the Eroxon group withdrew from treatment. The others who withdrew from Eroxon group were for lost to follow-up and re-location. The one patient who withdrew from tadalafil group was due to lost to follow-up.

A total of 87 patients, 41 (85.4%) in the Eroxon group and 46 (95.8%) in the tadalafil group, completed 24 weeks of treatment and the investigation.

Table 3 below summarizes the participant disposition throughout the study.

Table 3: Patient Disposition (All Enrolled Patients)

Number of Patients	**Eroxon N = 48 n (%)**	**Tadalafil N = 48 n (%)**	**All N = 96 n (%)**
Randomized	48 (100)	48 (100)	96 (100)
Country of enrollment			
Georgia	16 (33.3)	14 (29.2)	30 (31.3)
Poland	26 (54.2)	28 (58.3)	54 (56.3)
Bulgaria	2 (4.2)	1 (2.1)	3 (3.1)
United States	4 (8.3)	5 (10.4)	9 (9.4)
Received study treatment	47 (97.9)	47 (97.9)	94 (97.9)
Completed study investigation	41 (85.4)	46 (95.8)	87 (90.6)
Did not complete investigation	7 (14.6)	2 (4.2)	9 (9.4)
Reason for not completing			
Did not use treatment[1]	1 (2.1)	1(2.1)	2 (2.1)
Lack of effectiveness[2]	3 (6.3)	0 (0.0)	3 (3.1)
Lost to follow-up	1 (2.1)	1 (2.1)	2 (2.1)
Moved out of country	2 (4.2)	0 (0.0)	2 (2.1)

[1] Consent withdrew prior to using treatment
[2] Lack of effectiveness was considered as a reason adversely related to treatment

Demographic and Baseline Data

The majority of male patients in each treatment group were White, with 87 (90.6%) patients overall. The remaining 9 (9.4%) were Black or African Americans, 4 in the Eroxon group and 5 in the tadalafil 5 mg group. The age range across all treatment groups was 22 to 68 years. The majority of the female partners in each treatment group for the Full Analysis Set was White, with 87 (90.6%) patients. The remaining 9 (9.4%) were Black or African American. While the study did not enroll patients of Hispanic descent, this device is not expected to perform differently in this population compared to the general US population. The age range for female partners across all treatment groups was 19 to 69 years. The mean age was 43.8 years at baseline between the groups.

The randomized groups were comparable with respect to the ED disease status but the patients in the tadalafil group were younger on average than the ones in the Eroxon group. Recruitment was stratified by ED severity with the aim to randomize and treat approximately 40 mild ED patients, 36 moderate ED patients, and 24 severe ED patients. The actual number of patients was 38, 34, and 24 for mild, moderate, and severe ED patients, respectively.

The demographics and baseline characteristics of the randomized subjects is provided in **Table 4**:

Table 4: Demographics and baseline characteristics of randomized subjects

Characteristics		**Eroxon N = 48**	**Tadalafil N = 48**	**All N = 96**
Age (years)	Mean (SD)	46.1 (13.5)	41.5 (11.5)	43.8 (12.7)
	Median	44.5	39.0	40.5
	Minimum, Maximum	22, 68	23, 68	22, 68
Gender	Male	48 (100%)	48 (100%)	96 (100%)
	Female	0 (0%)	0 (0%)	0 (0%)
Race	White/Caucasian	44 (91.7%)	43 (89.6%)	87 (90.6%)
	Black/African American	4 (8.3%)	5 (10.4%)	9 (9.4%)
	Hispanic	0 (0%)	0 (0%)	0 (0%)
	Other	0 (0%)	0 (0%)	0 (0%)
ED duration (months)	Mean (SD)	28.93 (32.34)	27.28 (24.77)	8.11 (28.66)
	Median	16.02	16.15	16.15
	Minimum, Maximum	3.9, 164.6	5.1, 88.4	3.9, 164.6
	< 18 months	28 (58.3%)	27 (56.3%)	55 (57.3%)
	≥ 18 months	20 (41.7%)	21 (43.7%)	41 (42.7%)
ED Severity	Mild	19 (39.6%)	19 (39.6%)	38 (39.6%)
	Moderate	17 (35.4%)	17 (35.4%)	34 (35.4%)
	Severe	12 (25.0%)	12 (25.0%)	24 (25.0%)

Effectiveness Analysis

The IIEF-EF change from Baseline at week 24 is provided in **Table 5**:

Table 5: IIEF-EF Change from Baseline at Week 24 – t-test (Full Analysis Set, Eroxon group)

IIEF-EF	**Eroxon N = 48**
Week 24	
n	48
Mean (SE)	5.73 (1.00)
95% CI for mean	3.767, 7.701
t-statistics	5.71
One sided p-value[1]	<0.001

CI = Confidence Interval; SE = Standard error

[1] p-value from one-sample t-test against null hypothesis

Both co-primary endpoints were met. The mean change of 5.73 in IIEF-EF from baseline is clinically meaningful per the MCID. For the responder analysis, the sponsor used the improvement greater than 4 in IIEF-EF (MCID) to define a responder. The responder rate was 62% and is a clinically meaningful response rate considering the risks associated with the device.

For the secondary effectiveness endpoint analysis, 62.6% of subjects noticed an erection by 10 minutes and 55.7% of subjects were able to have penetrative sex within 15 minutes of Eroxon application.

The key exploratory endpoint evaluated the IIEF-EF responder rate at 24 weeks by ED severity. Over the 24-week treatment period, the mild ED group saw a 55% improvement, the moderate group saw a 45% improvement, and the severe ED group saw an 86% improvement.

Safety Analysis

Overall, more adverse events were reported in the tadalafil group (46.8% [22/47]) patients compared with the Eroxon group (36.2% [17/47]). One patient (2.1%) in the Eroxon group and 2 patients (4.3%) in the tadalafil group had reported adverse events that were considered to be treatment related. The TEAEs that were considered related to treatment were: a burning sensation at the site of application in one Eroxon group patient and headache in the two tadalafil group patients.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The Eroxon labeling consists of the package label and the package insert. 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 801.60 for over-the-counter devices. The package labeling includes indications for use, warnings, instructions for use, storage and use instructions, and Eroxon ingredients. The package insert includes indications for use, device description, contraindications, warnings, precautions, summary of the clinical study, instructions for use, storage information and frequently asked questions.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a non-medicated topical formulation for treatment of erectile dysfunction and the measures necessary to mitigate these risks.

Risks to Health	**Mitigation Measures**
Failure to identify correct population and condition, leading to ineffective use	Labeling
Deleterious effect on condoms leading to pregnancy or transmission of sexually transmitted infections	Non-clinical performance testing Labeling Shelf-life testing
Adverse tissue reaction	Biocompatibility evaluation Labeling Non-clinical performance testing
Pain or discomfort	Non-clinical performance testing Labeling Shelf-life testing

SPECIAL CONTROLS

In combination with general controls of the Food Drug & Cosmetic Act, a non-medicated topical formulation for treatment of erectile dysfunction is subject to the following special controls:

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

(2) 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) Condom compatibility;
   (ii) Temperature profile evaluation; and
   (iii) Verification of device specifications.

(3) Performance data must support the shelf life of the device by demonstrating the device meets its specifications over the identified shelf life.

(4) Labeling must include:
  (i) Information regarding compatibility with condoms;
  (ii) Expiration date;
  (iii) A statement that the product is not a contraceptive;
  (iv) Information for the correct diagnosis of erectile dysfunction; and
  (v) Dosage and frequency of use.

BENEFIT-RISK DETERMINATION

The benefits and risks of the device are based on data collected in the pivotal clinical study described above. The non-clinical testing data collected did not affect the benefit-risk determination.

Regarding the probable risks, one adverse event was reported in the pivotal study which related to mild device related discomfort (penile burning (mild) at the application site). This adverse event resolved after the cessation of device usage.

Regarding the probable benefits, in the pivotal study, there was a mean change in the IIEF-EF from baseline to week 24 of 5.73. This was a clinically meaningful improvement in IIEF-EF. The pivotal study successfully met the primary effectiveness endpoint by demonstrating an improvement greater than the minimally important clinical difference and a responder rate greater than 30%.

PATIENT PERSPECTIVES

The following patient reported outcomes were used in the pivotal study:

IIEF questionnaire: This questionnaire was used to assess the primary endpoint and exploratory endpoints. This questionnaire captured the improvement in erectile function compared to baseline.

Onset of action (erection) questionnaire: This questionnaire was used to assess the secondary endpoint. This questionnaire captured time-related events associated with sexual intercourse (i.e., when the patient and partner noticed the onset of an erection after the application of Eroxon and when the patient and partner were able to have penetrative sexual intercourse).

BENEFIT/RISK CONCLUSION

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

Treatment of erectile dysfunction in adult males aged 22 years and over.

The probable benefits outweigh the probable risks for Eroxon. 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 Eroxon is granted and the device is classified as follows:

Product Code: QWW
Device Type: Non-medicated topical formulation for treatment of erectile dysfunction
Class: II
Regulation Number: 21 CFR 876.5021