May 7, 2024

Pollogen Ltd.
% Amit Goren
Head of Regulatory Affairs
A. Stein Regulatory Affairs Consulting Company Ltd.
18 Hata'as St.
Kfar Saba, 4442518
Israel

Re: K233766
Trade/Device Name: Geneo X Elite
Regulation Number: 21 CFR 878.4420
Regulation Name: Electrosurgical Device For Over-The-Counter Aesthetic Use
Regulatory Class: Class II
Product Code: PAY
Dated: November 14, 2023
Received: November 24, 2023

Dear Amit Goren:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.05.07 09:22:31 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233766

Device Name

GENEO X ELITE

Indications for Use *(Describe)*

The GENEO X ELITE system with the TriPollar RF Applicator is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV.

The GENEO X ELITE system with the OxyGeneo Applicator is intended to provide massage by a mechanical vibration of an electrically powered applicator. The OxyGeneo treatment is suitable for all skin types.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

GENEO X ELITE DEVICE

510(k) Number K233766

Applicant Name:

Company Name: Pollogen Ltd.

Address: 6 Kaufman St. POB 50320
Tel-Aviv, 6801298
Israel
Tel: +972-3-5104110
Fax: +972-3-5104112
E-mail: amit@asteinrac.com

Contact Person:

Official Correspondent: Amit Goren

Company Name: A. Stein – Regulatory Affairs Consulting Ltd.

Address: 18 Hata'as Str.,
Kfar Saba 4442518, Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: April 07, 2024

Trade Name: GENEO X ELITE Device

Classification Name:
Main system platform:

21 CFR 878.4420, Class II, PAY

System Applicators:

The GENEO X device TriPollar RF Applicator unit: 21 CFR 878.4420, Class II, PAY

The OxyGeneo Applicator unit: 21 CFR 890.5660, Class I, ISA

Classification: Class II Medical Device

Predicate Device:

The subject device is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k) No.
Pollogen Ltd.	STOP U Model UXV	K220322

Device Description:

The GENEO X ELITE device is a non-invasive, tabletop console with a graphical user interface (GUI), which supports two applicator types: the TriPollar Radiofrequency (RF) Applicator utilizing bipolar radiofrequency technology for facial wrinkles treatments and the OxyGeneo Applicator utilizing mechanical vibration for facial massage sensation.

The GENEO X ELITE device is manufactured by Pollogen Ltd. Similar to the predicate device, the STOP U Model UXV device, the GENEO X ELITE device constitutes the same underlying TriPollar technology to employ bipolar RF energy in a non-invasive manner utilizing the TriPollar RF Applicator.

In addition to the TriPollar RF applicator the GENEO X ELITE device comprises the OxyGeneo Applicator. The OxyGeneo Applicator is an electrically powered massager utilizing mechanical vibration generated by an electrically powered motor housed in the applicator.

Following are the GENEO X ELITE device specifications:

General Specifications Conditions for Operation:	
Weight:	~9 Kg
Overall Dimensions:	418mm x 510mm x 223mm (H x W x D)
Input Voltage of Power Supply:	100-240V~50/60Hz,0.8-1.5A
Output Power Rating of Power Supply:	24VDC, 2.5A
Performance Specifications	
TriPollar RF Applicator Output Power	6W @ 200 OHM
TriPollar RF Applicator RF Frequency	1MHz
Massager Applicator speed range	300 – 1800±10% RPM
Environmental Conditions for Operation:	
Operating Temperature:	+5°C – +30°C
Operating Humidity:	20 – 80% RH
Atmospheric Pressure:	80 - 106 KPa
Operating Altitude:	2000 above sea level
Conditions for Transportation and Storage:	
Transport and Storage Temperature:	-20°C – +60°C
Transport and Storage Humidity:	5 – 90% RH
Atmospheric Pressure:	50 - 106 KPa
Preparation Gel Storage Conditions:	
Operating Temperature range	+5°C - +30°C When not in use, store securely closed in a cool and dry place below +30°C

Intended Use/Indication for Use:

The GENEO X ELITE device with the TriPollar RF Applicator is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV.

The GENEO X ELITE device with the OxyGeneo Applicator is intended to provide massage by a mechanical vibration of an electrically powered applicator. The OxyGeneo treatment is suitable for all skin types.

Performance Standards:

The GENEO X ELITE device complies with the following recognized consensus standards:

[Rec. Number 19-46] ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]

[Rec. Number 5-89] IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
[Rec. Number 19-36] 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
[Rec. Number 6-389] IEC 60601-2-2 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
[Rec. Number 13-79] IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

All the requirements of these standards were met. No adaptations were made to any of the test methods recommended in the standard. There were no applied deviations from the standard.

Non-Clinical (Bench) Performance Data:

The following validation activities were performed:

- Software Verification and Validation Testing
- Electrical safety and EMC testing
- Transportation and Environmental Testing
- Power control and RF accuracy testing
- Overheating testing
- Labeling Verification and Validation Testing
- Biocompatibility evaluation
- Service Life Analysis

All of the validation activities were performed using the same testing techniques and principles as performed using the predicate or reference devices. The results of the above

listed validation activities conclude that the GENEO X Elite device is safe and effective for its intended use and user population (both users and patients) and that the modified device is substantially equivalent to the predicate device.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Human Factors Validation Testing with the GENEO X ELITE device was performed to assess the user interface and RF applicator treatment protocol, including selection of the TriPollar RF applicator, turning on the GENEO X main unit, choosing basic system settings, providing treatment and cleaning, in the setting in which the device is intended to be used. The GENEO X workflow, training materials, and instructions were developed through formative assessment (Phase I) on the GENEO X TriPollar RF device (precursor to the GENEO X) in the EU (Belgium and Switzerland) and Canada.

The current GENEO X human factors (Usability) validation test further validated the GENEO X device and associated training materials, in a real-world environment in order to mitigate the residual usability risks (Phase II).

The Human Factors (Usability) study performed utilizing the GENEO X device was designed based on the Human Factors (Usability) study design conducted utilizing the reference device, the STOP U OTC device (K182744).

All aspects of the Human Factors / Usability study design were virtually identical in the GENEO X HF Study and in the previous STOP U HF study conducted with the reference device and demonstrate the substantial equivalence of the device to the main and reference devices and support the safety and effectiveness of the device.

Biocompatibility

All of the modified device materials which come in direct contact with the patient skin are biocompatible and identical to the materials used in the manufacturing of the predicate device or in other FDA cleared devices. Biocompatibility testing has been completed for all patient contacting material on the finished device. Biological testing passed successfully and included Cytotoxicity, Irritation, and Sensitization testing.

Substantial Equivalence:

The following tables provide comparison information for the GENEO X ELITE device and its primary predicate device; the STOP U Model UXV device.

	STOP U Model UXV ***Predicate Device; Pollogen Ltd. K220322***	**GENEO X ELITE** ***Modified device; Pollogen Ltd.***
1) Device Classification and Clinical Characteristics		
(a) Regulation Number	21 CFR 878.4420	21 CFR 878.4420 – TriPollar RF Applicator 21 CFR 890.5660 – OxyGeneo Massage Applicator
(b) Product Code	PAY	PAY – TriPollar RF Applicator ISA – OxyGeneo Massage Applicator
(c) Class	Class II	idem
(d) Manufacturer	Pollogen Ltd.	idem
(e) Prescription or OTC	OTC use (Lay persons)	OTC use (estheticians or cosmeticians)
(f) Target Population	Adults requiring treatment as specified in the indications for use.	idem
(g) Anatomical sites	Body parts requiring treatment as specified in the indications for use.	idem
(h) Environment Used	Home	Esthetic and cosmetology clinics.
(i) Indications For Use	The STOP U Model UXV device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV	The GENEO X device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV

	STOP U Model UXV ***Predicate Device; Pollogen Ltd. K220322***	**GENEO X (ELITE)** ***Modified device; Pollogen Ltd.***
2) Device Technological Characteristics		
(a) Device description / Design	The STOP U model UXV is a line powered, portable, software controlled, TriPollar RF applicator. The TriPollar RF applicator comprises the system control unit and RF generator.	The GENEO X is a line powered, tabletop, software controlled, platform system, including the TriPollar RF applicator. The system consists of the TriPollar RF Applicator and the OxyGeneo Applicator. The TriPollar RF Applicator comprises the system control unit and RF generator.
(b) Device components	The STOP U model UXV device consists of the following components: The STOP U Model UXV TriPollar RF Applicator unit, containing the following components: • Device head with four treatment electrodes and temperature sensor • RF Generator • Control unit (CPU) • Control panel which contains: o On/off button o Skin temperature ORANGE indicator LED light o RF status GREEN indicator LED light	The GENEO X device consists of the following components: The GENEO X TriPollar RF Applicator unit, containing the following components: • Device head with four treatment electrodes and temperature sensor • RF Generator • Control unit (CPU) • Control panel which contains: o On/off button o Skin temperature ORANGE indicator LED light

	STOP U Model UXV ***Predicate Device; Pollogen Ltd. K220322***	**GENEO X (ELITE)** ***Modified device; Pollogen Ltd.***
	The STOP U Model UXV power supply unit	○RF status GREEN/BLUE indicator LED light ○RF output power • The OxyGeneo Applicator massager The GENEO X power supply unit and an adaptor The device tabletop console contains: • A touchscreen with a mounted cradle bar (on the front panel) • Applicator cradles (on front panel) located on the cradle bar and connectors (on rear panel)
(c) Performance specifications	Input power: 100-240V, 50-60 Hz, 0.4A	Input power: 100-240V, 50-60 Hz, 1.5A (same as in reference OTC device STOP U K182774)
(d) Physical specifications	Dimensions: 32mm W x 51mm D x 134mm H Weight: 85 gr	TriPollar RF Applicator: Dimensions: 15mm W x 37mm D x 200mm H Weight: 144 gr Tabletop Console: Dimensions: 510mm W x 195mm D x 418mm H Weight: 9 Kg
(e) Output current	1.5A	2.5A (same as in reference OTC device STOP U K182774)

	STOP U Model UXV ***Predicate Device; Pollogen Ltd. K220322***	**GENEO X (ELITE)** ***Modified device; Pollogen Ltd.***
(f) Energy levels	1	1
(g) Maximal RF output power	5.7 W ±10%	6.0 W ±20%
(h) RF Frequency	1 MHz ±10%	idem
(i) Total Power Density (fluence)	5.7 W/cm^2 ±10%	6.0 W/cm^2 ±20%
(j) Pulse Duration	Continuous	idem
(k) Waveform	Biphasic	idem
(l) Wave Shape	Sinusoid	idem
3) Safety and Adherence to Consensus Standards		
(a) Safety features	The STOP U Model UXV device incorporates the following safety features. All personnel operating the system should be familiar with these features. • During activation, the System performs a self-test of the hardware. • Temperature of the treatment area is constantly monitored during the treatment. RF energy delivery is terminated when temperature reaches the Cut-off level. • System starts at default settings. • LED indicators positioned on the applicator body provide the operator with useful treatment information on treatment temperature and RF emission.	The GENEO X device incorporates the following safety features. All personnel operating the system should be familiar with these features. • During activation, the System performs a self-test of the hardware. • Temperature of the treatment area is constantly monitored during the treatment. RF energy delivery is terminated when temperature reaches the Cut-off level. • System starts at default settings. • LED indicators positioned on the applicator body provide the operator with useful treatment information on

	STOP U Model UXV ***Predicate Device; Pollogen Ltd. K220322***	**GENEO X (ELITE)** ***Modified device; Pollogen Ltd.***
	• The device complies with applicable electrical and mechanical standard requirements according to IEC 60601-1 and with the applicable RF standard IEC 60601-2-2. • The device complies with applicable EMC emissions and immunity standard requirements according to IEC 60601-1-2.	treatment temperature and RF emission. • The device complies with applicable electrical and mechanical standard requirements according to IEC 60601-1 and with the applicable RF standard IEC 60601-2-2. • The device complies with applicable EMC emissions and immunity standard requirements according to IEC 60601-1-2. • System has unique password to avoid device operation by unauthorized personnel. • The TriPollar RF power cannot be activated unless the designated applicator has been connected to the System. • Changes in the TriPollar RF applicator treatment duration will cause the device to stop and enter stand-by mode. The operator must select the desired treatment duration from the TriPollar Menu and resume applicator power

	STOP U Model UXV ***Predicate Device; Pollogen Ltd. K220322***	**GENEO X (ELITE)** ***Modified device; Pollogen Ltd.***
		activation by pressing the On/Off button directly from the applicator. • The device GUI provides useful information and messages including alerts for improved user compliance.
(b) Compatibility with Environment and Other Devices	STOP U Model UXV is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
(c) Electrical Safety	Power Requirements: 100-240 VAC 50-60 Hz The STOP U Model UXV is compliant with the IEC 60601-1 standard.	idem
(d) Mechanical Safety	The STOP U Model UXV is compliant with the IEC 60601-1 standard.	idem
(e) Chemical Safety	N/A	N/A
(f) Thermal Safety	The STOP U Model UXV is compliant with the IEC 60601-1 standard.	idem
(g) Radiation Safety	The STOP U Model UXV is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem
(h) Biocompatibility	All of the device materials that come in direct contact with the human skin are biocompatible. Biocompatibility testing has been completed for all patient contacting material on the finished device.	idem

	STOP U Model UXV ***Predicate Device; Pollogen Ltd. K220322***	**GENEO X (ELITE)** ***Modified device; Pollogen Ltd.***
	Biological testing passed successfully and included Cytotoxicity, Irritation, and Sensitization testing.	

Comparison Discussion:

The GENEO X device is a desktop, computerized, software-controlled device comprising a console with a touchscreen, applicator cradles, and two treatment applicators, the TriPollar RF applicator intended for treatment of mild to moderate wrinkles and the OxyGeneo mechanical massager applicator.

The intended use of the GENEO X device is identical to the intended use of the predicate STOP U Model UXV device (K220322), i.e. treatment of mild to moderate facial wrinkles. The GENEO X device is an OTC device, designed for qualified estheticians or cosmeticians use for use in esthetic and cosmetology clinics. It is not intended for use by laypersons and will not be sold to retail stores or pharmacies, but directly to qualified estheticians or cosmeticians.

The GENEO X TriPollar RF applicator is based on the same underlying RF technology as employed in the predicate STOP U Model UXV TriPollar RF applicator device. The mechanism of action and mechanism of operation are essentially identical to that of the predicate device. Minor modifications were made in the GENEO X TriPollar RF applicator, which do not raise new questions of safety or effectiveness. The modified specifications are extremely slight and therefore, the GENEO X TriPollar RF applicator is substantially equivalent to the specifications of the STOP U Model UXV predicate device.

The addition of the console with the touchscreen and the applicator cradles also do not raise new questions of safety or effectiveness. The subject device and predicate device present almost identical performance specifications (for the specified indications for use)

and integrate a set of similar safety features. The GENEO X device presents some additional safety features mainly related to the information that is provided to the user in the GUI. The minor differences in the technological characteristics between the subject device and predicate device do not raise new safety or effectiveness concerns. Furthermore, the subject device underwent performance testing including software validation testing, electrical and mechanical safety testing, EMC testing and specific bench testing, including RF output power testing and thermal overheating validation testing.

All of the above-mentioned performance test protocols were designed and performed in the same manner as the predicate device or the reference devices and the test results demonstrated that the GENEO X device has successfully passed the tests and that all of the device requirements were met.

Furthermore, the GENEO X device was also tested for human factors and usability. The human factors study was also designed in the same manner as the previous human factors study performed with the STOP U OTC reference device (K182774). The study involved use of the device by the device target users (estheticians / cosmeticians) and performing device operation and knowledge tasks. The human study / usability study results demonstrated that the GENEO X device is easy to operate, and the user manual is adequate for its purpose of instructing users how to operate and maintain the device.

Consequently, it can be concluded that the GENEO X device is substantially equivalent to the predicate, STOP U Model UXV device, (FDA-cleared in 510(k) K220322) and therefore, may be legally marketed in the USA.