February 17, 2022

Pollogen Ltd.
% Kathy Maynor
Regulatory Consultant
Kathy Maynor
26 Rebecca Ct
Homosassa, Florida 34446

Re: K220124
Trade/Device Name: YandR System, VoluDerm Handpiece and VoluDerm Tips
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 17, 2022
Received: January 18, 2022

Dear Kathy Maynor:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220124

Device Name
YandR System and VoluDerm Handpiece and VoluDerm Tips

Indications for Use *(Describe)*
The YandR System is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Handpiece.

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

The YandR System (member of the Legend Pro Family of Radio Frequency (RF) Systems)

Applicant Name: (21 CFR 807.92(a)(1)	Pollogen Ltd. 6 Kaufman Street Tel Aviv, Tel-Aviv, ISRAEL 6801298 Phone: +972 3 5104110 Fax: +972 3 5104112	
Contact Person: (21 CFR 807.92(a)(1)	Kathy Maynor Regulatory Consultant 26 Rebecca Ct Homosassa Florida 34446 Phone: 352-586-3113	*and* Amaya De Levie Lumenis Be Ltd. 6 Hakidma Street PO Box 240, Yokneam Industrial Park Yokneam 2069204 Israel Phone: +972-549599073 E-mail: Amaya.de-levie@lumenis.com
Date Prepared:	17 January 2022	
Trade Name: (21 CFR 807.92(a)(2)	YandR System and VoluDerm Handpiece and VoluDerm Tips	
Classification Name:	Powered laser surgical instrument	
Product Code:	GEI	
Device Class:	Class II	
Regulation Number:	21 CFR Part 878.4400	
Panel:	General & Plastic Surgery	
Predicate Devices: (21 CFR 807.92(a)(3)	Pollogen Legend+ system (K173503)	

Intended Use/ Indications for Use (21 CFR 807.92(a)):

The YandR System is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Handpiece.

Device Description (21 CFR 807.92(a)(4):

The YandR System, subject of this submission as well as the cleared systems of the Legend Pro RF Family of Systems (Pollogen Legend+ system (listed as Legend Pro); see K122200, K131758, K171359 and K173503) are computer-controlled RF devices connected to a treatment Handpiece/Applicators and disposable tips. The system is comprised of:

- System Console
- VoluDerm Handpiece/Applicator and single-use sterile removable tips (present only in the Surgen, Legend Pro and YandR Systems)

The YandR System with its VoluDerm Handpiece is a new model of the modified Legend Pro Family of RF Systems The YandR System as the cleared Pollogen Legend+ system can generate a 1MHz sinusoidal signal applied by the VoluDerm Handpiece and the same VoluDerm Tips with bi-polar electrode pins at up to 62 Joules/per pin. The proposed system relies on the same fundamental underlying technology of the cleared systems with some hardware and software modifications to meet the marketing requirements for a more compact and simple device (tabletop console instead of a floor-mounted, rolling console) with a modern interface and the support of only the VoluDerm Handpiece (removing the TriPollar Applicators), similarly to its predecessor, the Pollogen Ltd.'s Surgen U (K131758). Also, to simplify the system, the YandR system has a hand switch, integrated into the VoluDerm Handpiece (called the Handpiece Trigger), instead of a separated Footswitch.

The new member of the of the cleared Legend Pro Family of Radio Frequency (RF) systems (Apollo, Surgen and Pollogen Legend+ systems) is a class II electrosurgical cutting and coagulation device (21 C.F.R. §878.4400; Product Code GEI). The subject Y&R System with its VoluDerm Handpiece and VoluDerm Tips can be regarded as a modification of the Pollogen Legend+ System, a member of the Legend Pro Family of RF systems and accessories. As such, it shares with the cleared family members the same subset of intended use when using VoluDerm Handpiece and underlying technology. The subject modified YandR System with the VoluDerm Handpiece is claimed to be equivalent, regarding both its intended use and its technological characteristics to its cleared Pollogen Legend+ system, member of Legend Pro Family of RF Systems.

Substantial Equivalence (21 CFR 807.92(a)(6)

The YandR System, subject of this submission, is a modification of the Pollogen Legend+ system, recently cleared under. It is regarded as a modified member to the Legend Pro Family of RF Systems (cleared under K122200, K131758, K171359 and K173503). As such it shares with the cleared family members, the same intended use and underlying technology. The modifications introduced to the subject YandR System as compared to its cleared predicate are designed and intended mainly for system modernization and increased user convenience in accordance with market/design inputs.

Design verification and validation processes were performed as a result of this risk analysis assessment to verify that no different questions of safety and effectiveness have been raised due

to the modifications to this system. The test methods are essentially the same as those used to support to the clearance of the Pollogen Legend Pro+ (see K171359 and K173503 for the latest clearances).

The following activities were performed (21 CFR 807.92(b)(1):

- Risk analysis per ISO 14971
- Electrical, Radio Frequency and electromagnetic compatibility safety testing according to IEC 60601-1, IEC 60601-1-2, IEC and 60601-2-2
- Software verification and validation according to IEC 62304 and FDA Guidance “Principles of Software Validation Guidance for Industry and FDA Staff, January 2002”.
- System testing (e.g., energy measurements, safety controls, emission indicator, scanners, aiming beam).

Test results indicated that the YandR System performs in accordance with its requirements and specifications similarly to its predicate Pollogen Legend+ system member of the Legend Pro Family of RF Systems (cleared under K122200, K131758, K171359 and K173503). Consequently, Pollogen Ltd. believes that the YandR System is substantially equivalent to the cleared predicate and it does not raise any different questions of safety and/or effectiveness (21 CFR 807.92(b)(2).