Medtek Skincare, LLC
℅ Susan Anthony-Dewet
FDA Consultant
FDA Regulatory Consultants, LLC
1604 NE 4th CT,
Ft. Lauderdale, FL 33301

September 17, 2019

Re: K183708
Trade/Device Name: Poly Clear
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: August 26, 2019
Received: August 27, 2019

Dear Susan Anthony-Dewet:

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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183708

Device Name
Poly Clear

Indications for Use *(Describe)*
The Poly Clear combination of Red (633nm±10nm) and Blue (417nm±10nm) is intended to emit energy in the red, blue regions of the light spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

K183708

This 510(k) summary of information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Submission Date: December 16, 2018

1. Submitter Information: FDA Regulatory Consultants, LLC – Susan Anthoney-DeWet
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Email: sue@fdaregulatoryconsultant.com

On behalf of Sponsor: MedTek Skin Care, Inc.
3 Depot St., Hudson Falls, NY 12839
Phone: 1-518-747-3310

2. General Information

2.1 Classification Name: Light Based Over-The-Counter Powered Light Based Laser For Acne

2.3 Proprietary Names: Poly Clear

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code: OLP

2.7 Regulation Medical Specialty: General & Plastic Surgery

2.8 Review Panel: Office of Device Evaluation (ODE)
Division of Surgical Devices (DSD)
General Surgery Devices Branch One - Light Based/Laser (GSDB1)

3. Predicate Device(s):

3.1 Predicate Device for All Red, All Blue treatment heads:

K081307- Omnilux Clear-U (PhotoTherapuetics, Inc)

3.2 Predicate Device for Combo red/blue head:

K180900-LED Light Therapy Device, Model: KN-7000C (UV Biotek, LLC (now Medtek Skin Care))

3.3 Reference Devices :

1. K151336 – LightStim Professional 2-Panel Light System (LED Intellectual)
2. K170187- Photodynamic Therapy Device (UV Biotek, LLC (now Medtek Skin Care))

4. Device Description:

The Poly Clear is a portable device that has three separate detachable treatment heads, each containing a total of 1,820 LEDs in the treatment head. The treatment head is attached to a lifting stand that is attached to the main frame on a rolling stand. The user interface for applying treatment is a key lock to power ON/Off the device and a display screen attached to the main frame that runs the software (password protected-lockout code, runs treatment time/ treatment heads) for the device. 6 pairs of protective eyewear are included with the device.

The Poly Clear is not intended to be used by laypersons. Poly Clear is intended to only be operated by a person who has been trained by the Sponsor according to their Customer Training Plan.

5. Indications / Intended Use:

The Poly Clear combination of Red (633nm±10nm) and Blue (417nm±10nm) is intended to emit energy in the red, blue regions of the light spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris. (Product Code: OLP)

6. Summary of technological characteristics of the device compared to the predicate device:

Table 1: Predicate Chart –(All Red and All Blue Treatment Heads)

Device	**Proposed Device Poly Clear (TBD)**	**Predicate Device Omnilux Clear-U (K081307)**	**Reference Device #1 LightStim Professional 2-Panel Light System (K151336)**	**Reference Device #2 Photodynamic Therapy Device Model:KN-7000A (K170187)**	**Remarks**
Wavelengths	633±10nm 417±10nm	633±6nm 415±5nm	630nm, 415nm	633±10nm 417±10nm	SE Note 1
Energy Level (mW/cm2)	All Red head: 60mW/cm^2±10mW/cm^2 All Blue head: 35mW/cm^2±10mW/cm^2	Red: 70 mW/cm^2 Blue: 40 mW/cm^2	Unknown	(1)Red head: 60mW/cm^2±10mW /cm^2 (2)Blue head: 35mW/cm^2±10mW /cm^2	Similar to Predicate, identical to Reference Device# 2 SE Note 2
Modes	ON/OFF	Three position switch: Off – ON Blue –ON Red	ON/OFF	ON/OFF	SE Note 1
Power Supply	100-240V, 50/60Hz±2%, 300VA (Mains Connected)	AC to DC power supply (Mains Connected)	AC to DC power supply (Mains	100-240V, 50/60Hz±2%, 300VA	SE Note 1

			Connected)	(Mains Connected)	
Number of LEDs	Red Head: 1820 Blue Head: 1820	180 LEDs	1130 LEDs per Treatment Head	Red Head: 1820 Blue Head: 1820	Similar to Reference Device#1, Identical to Reference Device #2 SE Note 2
Treatment Area	800cm2	28.7cm2 ±10%	Unknown- 2 panels containing the LED array	800cm2	Similar to Reference Device #1, Identical to Reference Device #2 SE Note 2
Type and distance from skin	Panels containing LED array- 6cm distance	Handheld, against the skin	Panels containing LED array- unknown distance	Panels containing LED array- 6cm distance	Identical to Reference Devices 1 & 2 SE Note 2

Table 2: Poly Clear (Combo -Treatment head contains red and blue LEDs)

Device	**Proposed Device Poly Clear (TBD)**	**Predicate Device LED Light Therapy Device Model:KN-7000C (K180900)**	**Reference Device #1 LightStim Professional 2-Panel Light System (K151336)**	**Reference Device#2 Photodynamic Therapy Device Model:KN-7000A (K170187)**	**Remarks**
Wavelengths	633±10nm 417±10nm	633±10nm 417±10nm	630nm, 415nm	633±10nm 417±10nm	SE Note 1
Energy Level (mW/cm2)	Combo Red/Blue head: Red: 30mW/cm^2±10 Blue: 20mW/cm^2±10	Red: 45mW/cm^2±5 Blue: 25mW/cm^2±5	Unknown	(3)Red/Blue head: ●Red LEDs 30mW/cm^2±10mW/cm^2 ●Blue LEDs 20mW/cm^2±10mW/cm^2	SE- Similar to Predicate, Identical to Reference Device #2 SE Note 1
Modes	ON/OFF	ON/OFF	ON/OFF	ON/OFF	SE Note 1
Power Supply	100-240V, 50/60Hz±2%, 300VA (Mains Connected)	Rechargeable Li-Ion Batteries, with AC to DC power supply	AC to DC power supply (Mains Connected)	100-240V, 50/60Hz±2%, 300VA (Mains Connected)	Similar to Reference Device SE Note 2
Number of LEDs	Red:910 Blue: 910	Red:48 Blue:48	1130 LEDs per Treatment Head	Red:910 Blue: 910	Similar to Reference

					Device SE Note 2
Treatment Area	800cm2	26cm2 ±10%	Unknown- 2 panels containing the LED array	800cm2	Similar to Reference Device SE Note 2
Type and distance from skin	Panels containing LED array- 6cm distance	Handheld, against the skin	Panels containing LED array- unknown distance	Panels containing LED array- 6cm distance	Similar to Reference Device SE Note 2

SE Note 1: The Poly Clear device has the same indications for use, wavelengths, similar treatment regimen, and modes of operation with similar power output as their cited predicate device.

SE Note 2: The main technological differences between the Poly Clear device and the predicate devices are the number of LEDs, treatment area, type and distance used from skin (panel vs. handheld), power supply (battery vs mains), and intended operators of the device (OTC with Training provided by the sponsor). However, the Poly Clear device is similar to the reference device Photodynamic Therapy Device Model:KN-7000A (K170187) and similar to the reference device LightStim Professional 2-Panel Light System device (K151336) in these areas.

The sponsor is certain that the differences in the number of LEDs, treatment surface area, and distance used from skin (panel vs. handheld), does not affect the safety or efficacy of the device as there are a wide range of devices that have used predicate devices with different number of LEDs, different treatment areas, and panel vs handheld/mask devices cleared under device code OHS with no clinical studies required.

Performance Data i.e. bench testing and safety testing included in this submission shows that the Poly Clear device is substantially equivalent to the predicate and reference devices.

7. Performance Data/Non-Clinical Testing:

The conclusions drawn from the nonclinical testing below demonstrate that the Poly Clear device is substantially equivalent to the legally marketed devices identified in section 3.

Safety Testing

The Poly Clear device has been tested and conforms to international consensus standards:

ELECTRICAL SAFETY:
Recognition Number 19-4:

- IEC60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

EMC:
Recognition Number 19-8:

- IEC 60601-1-2:2014 Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance-Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

LAMP SAFETY:
Recognition Number 12-249:

- IEC 62471 First Edition 2006-07, Photobiological Safety Of Lamps And Lamp Systems. (Radiology)

DEVICE SPECIFIC SAFETY:
Recognition Number 12-242:

- IEC 60601-2-57:2011 Medical Electrical Equipment - Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use

The Poly Clear device has been tested to ensure the device meets specifications:

BENCH TESTING:

- **Software Validation Testing**
  The Poly Clear device's software was tested and validated in accordance with FDA's *"Guidance for the content of Premarket Submissions for Software Contained in Medical Devices."*

PERFORMANCE TESTING:

The performance bench tests include tests for Spectral Transmittance of Eyewear, Power density, Timer and Functions Test, Electrical Safety Test, Use Life Test, and Storage Condition Test.

USABILITY TESTING:
The sponsor conducted a Usability/Label Comprehension study to acquire data in order to evaluate and measure labeling comprehension, device usability, and training effectiveness by "intended users" of the Poly Clear device.
The results of this testing on the final version of the labeling and training plan showed that training was effective and intended users were able to understand the labeling and apply this information to device use for the primary operating functions of the device.

8. Substantial Equivalence Conclusion

After an analysis of the safety, indications, intended uses, performance, design materials, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device

and the predicate and reference devices and no new issues arise for safety and effectiveness. Therefore substantial equivalency is hereby requested.