October 13, 2017
Clarteis
% Allison Komiyama, Ph.D., RAC
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn St.
San Diego, California 92104

Re: K171702
Trade/Device Name: Exciplex308nm
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC, GEX
Dated: September 18, 2017
Received: September 19, 2017

Dear Dr. Komiyama:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K171702

Device Name
Exciplex308nm

Indications for Use *(Describe)*
The Exciplex308nm is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K171702

DATE PREPARED
October 13, 2017

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PROPRIETARY NAME OF SUBJECT DEVICE
Exciplex^{308nm}

COMMON NAME
Light, Ultraviolet, Dermatological

DEVICE CLASSIFICATION
Ultraviolet lamp for dermatologic disorders
(21 CFR 878.4630, FTC, Class II)

PREMARKET REVIEW
ODE/DSD/General Surgery Devices Branch One (GSDB1)
General & Plastic Surgery

INDICATIONS FOR USE
The Exciplex^{308nm} is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma.

DEVICE DESCRIPTION
The Exciplex^{308nm} is a compact handheld excimer device that emits a narrow-band UVB light at 308nm. This ultraviolet wavelength of light is known to be beneficial in the treatment of various dermatological conditions such as psoriasis and vitiligo. The UVB light is homogeneously

delivered through a 5x5cm^2 output window at an irradiance of 100mW/cm^2. Treatments are performed by applying the output window over the affected area with the help of treatment tips or silicone masks to shield the surrounding healthy skin. A treatment might consist of a series of light "shots" where the device is used multiple times along the affected area.

PREDICATE DEVICE IDENTIFICATION

The Exciplex^{308nm} is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K073066	Model 308 Dermatological Excimer System / Quantel Medical, Inc.	✓
K150752	GME ExSys 308 / GME German Medical Engineering GmbH	
K051428	VTRAC Excimer Lamp System / PhotoMedex, Inc.	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Exciplex^{308nm}. The following tests were performed to demonstrate safety based on current industry standards:

Software Verification: The software development and testing was executed in compliance to IEC 60601-1, IEC 62304 and ISO 14971.

Electromagnetic Compatibility and Electrical Safety: The subject device was tested in compliance to IEC 60601-1, IEC60601-1-2 and IEC 60601-2-57.

Performance and usability testing: The subject device was tested in compliance to IEC 62471, IEC 62366-1 and IEC 60601-1-6.

The results of these tests indicate that the Exciplex^{308nm} is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Clarteis believes that the Exciplex^{308nm} is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions, and uses similar materials as the device cleared in K073066. The subject device has the same intended use and similar technological characteristics (light source, wavelength, treatment area size, fluence range) to the devices cleared in K073066, K150752, and K051428. Any differences in technological characteristics do not raise different questions of safety and effectiveness and performance data demonstrate substantial equivalence to the predicates.

CONCLUSION

Based on the testing performed, including irradiance uniformity, ability of the masks and tips to block UV light, classification of the UV lamp, and software and hardware verification testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Exciplex^{308nm} are assessed to be substantially equivalent to the predicate devices.