December 11, 2019

Clarteis
% Lucie Dalet
Regulatory Consultant
Acknowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K191086
Trade/Device Name: Exciplex
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: April 23, 2019
Received: April 24, 2019

Dear Lucie Dalet:

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 post-marketing 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,

Purva Pandya
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191086

Device Name
Exciplex

Indications for Use *(Describe)*
The exciplex® is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. The reusable polycarbonate/ABS reduction tips and reusable silicone masks are for use on intact skin only.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K191086

DATE PREPARED
December 5, 2019

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Exciplex
Common Name:	Light, Ultraviolet, Dermatological
Regulation Number:	21 CFR 878.4630
Class:	II
Product Code:	FTC
Premarket Review:	ODE/DSD/General Surgery Devices Branch One (GSDB1)
Review Panel:	General & Plastic Surgery

PREDICATE DEVICE IDENTIFICATION
The Exciplex is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K171702	Exciplex^{308nm}/ Clarteis	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The Exciplex is a compact handheld excimer device that emits a narrow-band UVB light at 308 nm. 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 5x5 cm^2 output window at an irradiance of 100 mW/cm^2. Treatments are performed by applying the output window over the affected area with the help of reduction tips or silicone masks to shield the surrounding healthy skin. A treatment might consist of a series of light pulses where the device is used multiple times along the affected area.

510(k) Summary

INDICATIONS FOR USE

The Exciplex is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. The reusable polycarbonate/ABS reduction tips and reusable silicone masks are for use on intact skin only.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Clarteis believes that the Exciplex is substantially equivalent to the predicate device based on the information summarized here:

The subject device has identical design, dimensions and materials to the device cleared in K171702. The subject device has identical intended use and technological characteristics (light source, wavelength, treatment area size, fluence range) to the device cleared in K171702.

The main difference with the predicate device is the reprocessing of the existing silicone masks and reduction tips, whereas the predicate device components are provided for single-use only. Validation testing was conducted to ensure that the cleaning methods of the silicone masks and reduction tips are acceptable, and do not raise new issues of safety and effectiveness compared to the predicate device.

Minor software changes were also made to the subject device compared to the predicate device. These changes do not change the intended use of the device. Verification and validation testing were conducted to ensure that the software changes do not affect the safety and effectiveness of the subject device compared to the predicate device.

SUMMARY OF NON-CLINICAL TESTING

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

Reprocessing validation: the reprocessing of the reduction tips and silicone masks was validated per AAMI TIR 12:2010 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers* and AAMI TIR 30:2011 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*.

Software Verification: The software development and testing were executed in compliance to IEC 62304 *Medical device software – Software life cycle processes* and ISO 14971 *Medical devices - Application of risk management to medical devices*.

SUMMARY OF CLINICAL TESTING

No clinical data were provided in order to demonstrate substantial equivalence.

510(k) Summary

CONCLUSION

Based on the test results, the similar indications for use, and the similar technological characteristics, the Exciplex is considered to be substantially equivalent to the predicate device.