September 1, 2023

Xenex Disinfection Services, Inc.
% Jodi Scott
Partner
Hogan Lovells US LLP
1601 Wewatta Street, #900
Denver, Colorado 80202

Re: DEN230007
Trade/Device Name: LightStrike+
Regulation Number: 21 CFR 880.6510
Regulation Name: Whole room microbial reduction device
Regulatory Class: Class II
Product Code: QXJ
Dated: January 31, 2023
Received: February 1, 2023

Dear Jodi Scott:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the LightStrike+, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> The Xenex LightStrike™+ is a pulsed, broad-spectrum, high-intensity, germicidal UV light system intended to perform microbial reduction on non-porous, non-critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices. LightStrike+ is intended for use in unoccupied operating rooms, hospital rooms, and other clinical settings where non-critical medical devices are present as an adjunct to existing manual cleaning and disinfection practices. The system is for over-the-counter (OTC) use.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the LightStrike+, and substantially equivalent devices of this generic type, into Class II under the generic name whole room microbial redution device.

FDA identifies this generic type of device as:

> **Whole room microbial reduction device**. A whole room microbial reduction device is a medical device to be used to reduce microbial load on medical device surfaces following cleaning and disinfection.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On February 1, 2023, FDA received your De Novo requesting classification of the LightStrike+. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the LightStrike+ into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the LightStrike+ can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Exposure to microbiocidal agent, leading to skin and eye damage	Non-clinical performance testing Biocompatibility evaluation Software verification, validation, and hazard analysis Labeling
Respiratory mucous membrane irritation and pulmonary edema due to chemical exposure	Non-clinical performance testing Biocompatibility evaluation
Patient cross-contamination due to device failure leading to inadequate microbial reduction	Non-clinical performance testing Labeling Software verification, validation, and hazard analysis
Electrical shock	Electrical safety testing Non-clinical performance testing Labeling
Interference with other devices	Electromagnetic compatibility testing Electrical safety testing Wireless coexistence testing Labeling

In combination with the general controls of the FD&C Act, the whole room microbial reduction device is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Performance testing must demonstrate microbial log reduction of the demonstrated most resistant microorganism on medical device surfaces commensurate with the intended level of microbial reduction;
   (ii) Simulated use testing must evaluate device performance under simulated worst-case use conditions (e.g., soiling, room objects and surfaces, distances);
   (iii) In-use testing must evaluate device performance under real-world use conditions;
   (iv) Performance testing must demonstrate the photobiological safety of any lamps or lamp systems;
   (v) Performance testing must evaluate safety features intended to prevent exposure and ensure that device operation can only occur in an unoccupied environment; and
   (vi) Performance testing must characterize the long-term material compatibility of the microbiocidal agent on clinically relevant surfaces and/or devices.

(2) Biocompatibility testing must demonstrate safe residual levels of chemicals on medical devices surfaces and/or gaseous byproducts in air.

(3) Software verification, validation, and hazard analysis must be performed for any software components.

(4) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(5) Labeling must include:
   (i) Warnings and instructions to ensure the device is operated in an unoccupied environment;
   (ii) Setup and positioning instructions; and
   (iii) Information regarding material compatibility.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the whole room microbial reduction device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Paulo Laranjeira at 301-796-9024.

Sincerely,

David Krause -S

for Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health