December 3, 2021

Klox Technologies Inc.
Daniela Jukic
Senior Director, Regulatory Affairs, Compliance & Quality Assurance
275 boul. Armand Frappier
Laval, Quebec H7V 4A7
Canada

Re: DEN200005
Trade/Device Name: Klox Biophotonic LumiHeal System
Regulation Number: 21 CFR 878.4880
Regulation Name: Phototherapy device for reducing the appearance of acute post-surgical incisions
Regulatory Class: Class II
Product Code: QPE
Dated: January 30, 2020
Received: February 4, 2020

Dear Daniela Jukic:

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 Klox Biophotonic LumiHeal System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Klox Biophotonic LumiHeal™ System is indicated to provide blue light and fluorescent light energy for use on post-surgical incisions for scar management. The System is intended to be used in FST I-IV female patients 22 years and over.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Klox Biophotonic LumiHeal System, and substantially equivalent devices of this generic type, into Class II under the generic name phototherapy device for reducing the appearance of acute post-surgical incisions.

FDA identifies this generic type of device as:

> **Phototherapy device for reducing the appearance of acute post-surgical incisions**. This device consists of a light emitting device and a photoconverter gel and is intended to employ light energy for reducing the appearance of acute post-surgical incisions. This classification does not include products which contain drugs or biologics.

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 4, 2020, FDA received your De Novo requesting classification of the Klox Biophotonic LumiHeal System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Klox Biophotonic LumiHeal System 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 Klox Biophotonic LumiHeal System 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:

Identified Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterility testing Shelf life testing Labeling
Thermal damage and ocular injury	Non-clinical performance testing Thermal safety testing Labeling
Shock or burns from electrical malfunction or electromagnetic interference with other devices	Electrical safety testing Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis
Use error that may result in injury	Labeling Software verification, validation, and hazard analysis

In combination with the general controls of the FD&C Act, the phototherapy device for reducing the appearance of acute post-surgical incisions 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. Testing must include the following:
   (i) Verification and validation testing of the spectrum and power intensity of the light source;
   (ii) Heat dissipation from the area following device application; and
   (iii) Biophotonic properties of the photoconverter gel, including radiant fluence (transmitted light and fluorescence) delivered through the photoconverter gel by the device.
(2) The patient-contacting components of the device must be demonstrated to be biocompatible.
(3) Performance data must evaluate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the photoconverter gel by demonstrating continued sterility and functional performance over the identified shelf life.
(5) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device in the intended use environment.
(6) Software verification, validation, and hazard analysis must be performed for any software components.
(7) Labeling must include the following:
    (i) A summary of the device technical specifications, including light wavelength, irradiance and application area;
    (ii) Warnings for ensuring eye safety, including use of protective eyeglasses used for both the operator and the patient; and
    (iii) A shelf life for the photoconverter gel.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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 phototherapy device for reducing the appearance of acute post-surgical incisions 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 Yan Fu at 301-796-6278.

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