May 17, 2023

DeepX Health LLC
% Howard Schrayer
Official Correspondent
8 Lookout
Hilton Head Island, South Carolina 29928

Re: K230448
Trade/Device Name: DeepX DermoSight Dermatoscope
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: PSN
Dated: February 20, 2023
Received: February 21, 2023

Dear Howard Schrayer:

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,

Jessica Carr -S

Jessica Carr, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230488

Device Name
DeepX DermoSight Dermatoscope

Indications for Use *(Describe)*
The DeepX DermoSight Dermatoscope is a non-invasive skin imaging system, which acquires white light dermatoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Exhibit E - 510(k) Summary

Contact: Howard Schrayer
DeepX Health LLC
2101 L Street, NW Suite 300
Washington, DC 20037

Telephone: 609-273-7350
hs.ss@lucidmedical.net

Date Prepared: February 20, 2023

Device Trade Name: DermoSight Dermatoscope

Manufacturer: DeepX Health LLC
2101 L Street, NW Suite 300
Washington, DC 20037

Common Name: Light Based Imaging - Surgical Lamp

Classification: Class II

Product Code: PSN

Regulation: 21 CFR 878.4580

Predicate Devices:
Primary Predicate

Demetra BDEM-01
Surgical Lamp
[510(k) K192829]

Reference Predicate

Visiomed AG
MicroDERM® Model/Version 3.5
[510(k) K040171]

Indications for Use:

The DeepX DermoSight Dermatoscope is a non-invasive skin imaging system, which acquires white light dermatoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.

Device Description:

The DeepX Health DermoSight Dermatoscope is designed to acquire images of the skin and optimize the imaging storage and documentation workflow. The DeepX Health DermoSight Dermatoscope system consists of a hardware device and a software application. The hardware device is a hand-held, dermatoscope (camera) for acquiring and transmitting images of the skin. The hand-held, portable unit includes an LED light-source, a digital camera and a USB cable to transfer images to a standard PC workstation. The device acquires optical dermatoscopic images in a contact mode (acquired with the device in contact with the skin). In addition, the device can also acquire a clinical close-up image, when it is positioned 15cm from the skin.

The stand-alone software application is cloud-based software with a related web application. The cloud software allows for storage and retrieval of the acquired images and patient data for review by medical professionals.

DeepX Health DermoSight Dermatoscope software is a stand-alone application to be accessed via a standard computer connected to the hospital/clinic server or directly to the internet.

The software displays the patient demographic and identification information (e.g., date of image acquisition and anatomic location of photographed site). The images and identification data may be output to the computer used for image acquisition or downloaded to an alternate computer or storage device identified by the user.

Substantial Equivalence and Predicate Devices:

The device was shown to be substantially equivalent to a previously cleared light based imaging devices, specifically including the Demetra BDEM-01 system [510(k) K192829] predicate and the Visiomed AG MicroDERM® Model/Version 3.5 [510(k) K040171].

Performance Testing:

The following documentation was submitted in the 510(k).

Hardware Requirements
Level of Concern Statement
Software Description
Software Architecture Specification
User Manual and Instructions for Use
Software Design Specification
Risk Analysis
Traceability Matrix
Software Validation Report
Usability Evaluation Report
Software Development and Lifecycle Plan
Unresolved Anomalies
Cybersecurity
Electromagnetic Compatibility and Safety
Biocompatibility Data

Predicate Comparison Table

Manufacturer	**DeepX Health LLC**	**Demetra**
Trade Name	DeepX Health DermoSight Dermatoscope	Demetra BDEM-01
510(k) Number	Subject Device - TBD	K192829
Regulatory Class	Class II	Class II
Regulation	21 CFR 878.4580	21 CFR 878.4580
Type of Device/ Product Code / Regulation	Light Based Imaging Surgical Lamp PSN 21 CFR 878.4580	Light Based Imaging Surgical Lamp PSN 21 CFR 878.4580
Indications for Use	The DeepX DermoSight Dermatoscope is a non-invasive skin imaging system, which acquires white light dermatoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.	The Barco DermoSight Dermatoscope is a noninvasive skin imaging system, which acquires multispectral and white light dermatoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.
Intended Use (From Regulation)	A surgical lamp (including a fixture) is a device intended to be used to provide visible	A surgical lamp (including a fixture) is a device intended to be used to provide visible

	illumination of the surgical field or the patient. Emission and collection of light to create an image for medical purposes	illumination of the surgical field or the patient. Emission and collection of light to create an image for medical purposes
Intended Users	Trained medical practitioners	Trained medical practitioners
Mechanism of Action	Acquire and display of digital video images	Acquire and display of digital video images
Form of Hardware Component of Device	The hardware device is a portable, battery powered medical device for acquiring and visualizing images of the skin.	The hardware device is a portable, battery powered medical device for acquiring and visualizing images of the skin.
DermoSight Camera Resolution	5mp 2592 x 1944 CMOS sensor	8mp 3840 x 2160 CMOS sensor
Light Source	White light LEDs	White light LEDs Multispectral LEDs
Data transfer	Camera to PC via USB cable	FCC compliant wireless
Software location	Cloud based	Cloud based
Functions	Image acquisition Image transfer Image and patient data storage and retrieval Image display and comparison	Image acquisition Image transfer Image and patient data storage and retrieval Image display and comparison
Use environment	Professional medical environment	Professional medical environment
Hardware Location	PC inserted between image source (camera) and internet connection	PC inserted between image source (camera) and internet connection
Body contact	Unbroken skin	Unbroken skin
User interface	Proprietary software for entry and retrieval of patient identification, lesion location and images	Proprietary software for entry and retrieval of patient identification, lesion location and images
Biocompatibility	ISO 10993 for tissue contact nose piece and spacer	ISO 10993 for tissue contact nose piece
Environmental compatibility	IEC 60601-1-2:2014 and EN 60601-1-2:2015 compliant	IEC 60601-1-2:2014 and EN 60601-1-2:2015 compliant
Electrical safety	IEC 60601 compliant	IEC 60601 compliant

Conclusion

The DeeX Health DermoSight Dermatoscope system is substantially equivalent to the previously cleared Demetra BDEM-01 Image Processing System with respect to intended use, general technological characteristics and performance.