Barco NV
Imke Storm
Regulatory Affairs Officer
President Kennedypark 35
Kortrijk, W-LV 8500
Belgium

March 11, 2022

Re: K213957
Trade/Device Name: Demetra Dermatoscope BDEM-01
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: Class II
Product Code: PSN
Dated: February 10, 2022
Received: February 17, 2022

Dear Imke Storm:

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,

Neil R.P. Ogden, MS
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)*
K213957

Device Name
Demetra BDEM-01

Indications for Use *(Describe)*
The Barco Digital Dermatoscope is a non-invasive skin imaging system, which acquires multispectral and white light dermoscopic 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 (in accordance with 21 CFR 807.92)	
1. Company	Barco N.V. Healthcare Division 35 President Kennedypark 8500 Kortrijk BELGIUM
2. Contact person	Imke Storm Regulatory Affairs Officer Tel: +32 (0)470 189 293 Imke.storm@barco.com
3. Date of submission	November 29 2021
4. Device information	Trade name/model: Demetra BDEM-01 Common name: Dermatoscope Classification name: Light Based Imaging – Surgical lamp Classification code: PSN Regulation number: 878.4580
5. Predicate device	Demetra BDEM-01 – K192829
6. Device description	The Barco Demetra BDEM-01 is designed to capture images of the skin and optimize the imaging and documentation workflow. The "Barco Demetra BDEM-01" consists of a hardware device and a software application. The hardware device is a portable, battery powered medical device for acquiring and visualizing images of the skin. The device acquires multispectral optical dermoscopic images in a contact mode (device in contact with the skin). In addition, the device can also acquire a clinical close-up image, when it is held at up to 10 to 15 cm from the skin, and a clinical overview image when it is held at a distance of approximately 35-55 cm from the skin. The stand-alone software application is cloud software with a related web application. The cloud software can generate reports containing white light dermoscopic images and clinical photographs of the skin to be reviewed by trained medical practitioners.
7. Intended Use of the Device	The Barco Digital Dermatoscope is a non-invasive skin imaging system, which acquires multispectral and white light dermoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.

8. Comparison of technological characteristics	**Trade Name/Device Name**	**BDEM-01 (original K-192829)**	**BDEM-01 (this special 510(k))**
	Product Code	PSN	PSN

	Regulatory Class	II	II
	Indications for use	The Barco Digital Dermatoscope is a non-invasive skin imaging system, which acquires multispectral and white light dermoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.	The Barco Digital Dermatoscope is a non-invasive skin imaging system, which acquires multispectral and white light dermoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.
	Illumination for	Skin	Skin
	Intended users	Trained medical practitioners	Trained medical practitioners
	Where used	Professional environment	Professional environment
	Digital or Analog	Digital	Digital
	Illumination	White light LEDs (for live preview mode and dermoscopic images) Multispectral LEDs (for dermoscopic images) • Amber • Deep Red • Green • Cyan • Blue • Royal Blue • Far Red • Red-Orange (Only for acquisition and storage, not for visualization in the current intended use)	White light LEDs (for live preview mode and dermoscopic images) Multispectral LEDs (for dermoscopic images) • Amber • Deep Red • Green • Cyan • Blue • Royal Blue • Far Red • Red-Orange (Only for acquisition and storage, not for visualization in the current intended use)
	Magnification	10-50x fold (1 sensor pixel = 6.383um in contact)	10-50x fold (1 sensor pixel = 6.383um in contact)
	Sensor resolution	3840 (H) × 2160 (V) CMOS sensor	3840 (H) × 2160 (V) CMOS sensor

Barco nv | Beneluxpark 21 | B-8500 Kortrijk | Belgium
Registered office: President Kennedypark 35 | B-8500 Kortrijk | Belgium
IBAN BE49 3850 5234 2071 BBRUBEBB | VAT BE 0473.191.041 | RPR Gent, Section Kortrijk
www.barco.com

	Design	Camera, software and integrated AMOLED capacitive touchscreen	Camera, software and integrated AMOLED capacitive touchscreen
	Human factors	Handheld device	Handheld device
	Net weight scope	Without non–contact cone: 528 g With non–contact cone: 552 g	Without non–contact cone: 528 g With non–contact cone: 552 g
	Biocompatibility	Biocompatible (ISO 10993)	Biocompatible (ISO 10993)
	Data connection	Wireless communication FCC compliant	Wireless communication FCC compliant
	Compatibility with the environment and other devices	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

9. Performance testing

The bench tests mentioned below were performed to validate the device characteristics that differ from the predicate device in the original 510(k) K192829.

Modification to device	**Test performed**	**Criteria**
Multispectral Image Acquisition Workflow	Functionality Tested	PASS
Micro-chip	Functionality Tested	PASS
Supplier of the primary and secondary camera changed with identical specifications	Functionality Tested	PASS
Data acquisition, handling, and display	Functionality Tested	PASS
Inclusion of Analytics Toolkit (display of skin parameters map only, cleared via K201408)	Functionality Tested	PASS

10. Conclusion

Demetra BDEM-01 was found to be substantially equivalent to the predicate device, due to the following reasons:

a) Device and predicate device have the same intended use
b) The technological characteristics differences from the predicate device do not raise different questions of safety or effectiveness

	c) All hardware and software tests were performed since the first traditional 510(K) for BDEM-01 to make sure that all features work as intended. No safety or performance issues were reported.