



December 13, 2019

Barco NV
Julie Vandecandelaere
Regulatory Affairs Officer
President Kennedypark 35
Kortrijk, 8500 BE

Re: K192829
Trade/Device Name: Demetra BDEM-01
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: Class II
Product Code: PSN
Dated: September 30, 2019
Received: October 2, 2019

Dear Julie Vandecandelaere:

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,

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

Indications for Use

510(k) Number (if known)

K192829

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.

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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	Julie Vandecandelaere Regulatory Affairs Officer Tel: +32 (0)56 26 13 19 julie.vandecandelaere@barco.com
3. Date of submission	September 30 2019
4. Device information	Trade name/model: Demetra BDEM-01 Common name: Dermatoscope / Skin Analysis System Classification name: Light Based Imaging – Surgical lamp Classification code: PSN Regulation number: 878.4580
5. Predicate device	Microderm - K040171
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 also generate one or more reports and feedback to the device.
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. <i>This indication for use statement is equivalent to the one of the predicate device. The acquisition of multispectral images is not a critical difference for the use of the device and does not affect the safety or effectiveness of the device.</i>

8. Comparison of	Trade Name/Device Name	BDEM-01	MicroDERM (K040171)
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technological characteristics	Product Code	PSN	PSN (originally filed as FSS)	
	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.	MicroDERM is intended for the acquisition and storage of images of skin surfaces. These images can then be retrieved, printed, reviewed and displayed.	
	Illumination for	Skin	Skin	
	Intended users	Trained medical practitioners	Physicians	
	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	
	Magnification	10-50x fold (1 sensor pixel = 6.383um in contact)	15-50x fold	
	Sensor resolution	3840 (H) × 2160 (V) CMOS sensor	752 x 582 pixel CCD	
	Design	Camera, software and integrated AMOLED capacitive touchscreen	Camera, software and frame grabber card	
	Human factors	Handheld device	Handheld device + card	

	Net weight scope	Without non–contact cone: 528 g With non–contact cone: 552 g	2150 g	
	Biocompatibility	Biocompatible (ISO 10993)	Unknown	
	Data connection	Wireless communication FCC compliant	Model or network card	
	Compatibility with the environment and other devices	IEC 60601-1-2:2014 and EN 60601-1-2:2015 compliant	IEC 60601 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 <u>differ</u> from the predicate device:			
	Modification to device	Test performed	Criteria	
	Multispectral LEDs illumination	Per IEC 62471	PASS	
	Only hand-held and device with less weight	Usability Engineering	PASS	
	Biocompatibility	Biological Evaluation	PASS	
	Image acquisition	Review of sample images	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 affect safety or effectiveness c) Bench testing showed that the device has similar characteristics compared to the predicate device and did not reveal new issues of safety and performance.			