Barco NV
Julie Vandecandelaere
Regulatory Affairs Officer
President Kennedypark 35
Kortrijk, W-VL 8500
Belgium

February 18, 2021

Re: K201408
Trade/Device Name: Demetra Analytics Toolkit
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: Class II
Product Code: PSN
Dated: January 18, 2021
Received: January 21, 2021

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 and Part 809); 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, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201408

Device Name
Demetra Analytics Toolkit

Indications for Use *(Describe)*
The Barco Demetra Analytics Toolkit is a non-invasive skin analysis system. The Barco Demetra Skin Parameter Maps Tool provides maps that show the relative location of blood and pigment. The Barco Demetra Skin Parameter Maps Tool is intended only to complement dermoscopy.

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	
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	February 17 2021
4. Device information	Trade name/model: Demetra Analytics Toolkit Common name: Light Based Imaging Classification name: Surgical Lamp Classification code: PSN Regulation number: 878.4580 Regulatory class: 2
5. Predicate device	SIAscope V - Astron Clinica Limited - K062736
6. Device description	The Barco Demetra Analytics Toolkit is a software application used to support analysis of dermoscopic images captured with the Barco Demetra BDEM-01 dermatoscope (K192829). The system is intended for use by medical practitioners. Scatter Contrast Maps provide additional information to dermoscopy by highlighting surface contours. The Skin Parameter Maps Tool provides images generated from multispectral image sets and aids the user in visualizing blood and pigment patterns in the skin. The output of the Skin Parameter Maps is shown to the user as grayscale two-dimensional maps. The maps are intended only to complement dermoscopy.
7. Indications for Use of the Device	The Barco Demetra Analytics Toolkit is a non-invasive skin analysis system. The Barco Demetra Skin Parameter Maps Tool provides maps that show the relative location of blood and pigment. The Barco Demetra Skin Parameter Maps Tool is intended only to complement dermoscopy.

8. Comparison of technological characteristics

Trade Name/Device Name	Analytics Toolkit	SIAscope V
Product Code	PSN	PSN
Regulatory Class	II	II
Indications for use	The Barco Demetra Analytics Toolkit is a non-invasive skin analysis system. The Barco Demetra Skin Parameter Maps Tool provides maps that show the relative location of blood and pigment. The Barco Demetra Skin Parameter Maps Tool is intended only to complement dermoscopy.	The SIAscope is a non-invasive skin analysis system, which provides color bitmaps called 'SIAscans' that show the relative location of blood, collagen and pigment
Functionality	The Skin Parameter Maps are generated from multispectral image sets and aid the user in visualizing blood and pigment patterns in the skin. The output of the Skin Parameter Maps is shown to the user as grayscale two-dimensional maps.	SIAscans show the relative location of blood, collagen and pigment
Operating principle	Measuring intensity of remitted light based on Beer-Lambert principle	Measuring intensity of remitted light, based on Kubelka-Munk skin model
Analysis of images of	Skin	Skin
Where used	Professional environment	Professional environment
Digital or Analog images	Digital	Digital
Illumination of the compatible dermatoscope	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	LEDs both visible and near-infrared
Design	Only software, compatible with Barco's Demetra BDEM-01 dermatoscope (K192829)	Hardware dermatoscope + software (Dermetrics)

9. Performance testing

The following performance data were provided in support of the substantial equivalence determination.

Test performed	Result
Software Verification Testing	PASS
Usability Engineering Testing Design Validation, which includes integration testing with BDEM-01 device	PASS

The Demetra Analytics Toolkit software has a moderate level of concern.

Several clinical validation activities have been performed to support safety and effectiveness of the device. This included:

- A retrospective clinical study “Clinical validation of Demetra Skin Parameter Maps”. This retrospective reader study was performed by four board certified dermatologists from different sites in the USA. The selected dataset contains a mix of 28 cases, representing various dermatology conditions for which a dermatologist can use a dermatoscope during evaluation, with a focus on skin lesions suspicious for skin cancer. For each of the cases, all readers provided a subjective rating of the skin parameter maps corresponding to these cases. Statistical analysis was performed on the collected ratings. In addition qualitative feedback from the readers was also collected.

- A retrospective study “SIAScans vs. Barco Analytics Toolkit” performed by a board certified dermatologist from OHSU Dermatology Clinic, Portland. This study compared performance of the Barco skin parameter maps with performance of the predicate device (Siascope) for a representative set of specific types of cases. Contribution of ‘other’ signals to the maps (for both Siascope and Barco) was also included in the performance comparison.

- A prospective clinical study performed by a board certified dermatologist from Washington DC; and a dermato pathologist from Maryland. The study “Correlation of structures visualized in the Skin Parameter Maps with pathology findings” directly compared skin parameter maps with pathology H&E images for collected 15 cases. Subjective rating as well as qualitative case analysis was performed. Statistical analysis was performed on the collected ratings.

- A clinical study performed by a dermatologist from University Hospital Leuven in Belgium. This study “Validation of skin structures imaged in the Skin Parameter Maps” included 15 cases for which a dermatologist would typically use the skin parameter maps. Subjective rating as well as qualitative case analysis was performed. Statistical analysis was performed on the collected ratings.

- A clinical study performed at Charité Universitätsmedizin Berlin, Germany; and at a dermatology practice in Oregon, USA. Four observers participated in this retrospective reader study. 28 representative cases were collected from an existing database. Purpose of this study was to validate the skin parameter maps, and more specifically also to validate the device when used with and without liquid interface. All observers provided subjective ratings for every case. Statistical analysis was performed on the collected ratings.

10. Conclusion	Demetra Analytics Toolkit was found to be as safe, as effective, and performs as well as the legally marketed predicate device, due to the following reasons: a) Device and predicate device have a similar 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.