Barco NV
Lieven De Wandel
Regulatory Affairs Officer
President Kennedypark 35
Kortrijk, W-VL 8500
Belgium

April 15, 2021

Re: K203364
Trade/Device Name: MDPC-8127
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: PZZ
Dated: February 12, 2021
Received: February 22, 2021

Dear Lieven De Wandel:

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 post-marketing 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,

Soma Ghosh, Ph.D.
Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K203364

Device Name
MDPC-8127

Indications for Use *(Describe)*
The Barco MDPC-8127 device is intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device. It is an aid to the pathologist to review and interpret digital images of histopathology slides for primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using the MDPC-8127. The display is not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.

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

MDPC-8127

Company

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Contact person

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Date of submission

February 12, 2021

Device information

Trade name/model:	MDPC-8127
Common name:	Digital Pathology Display
Classification name:	Digital Pathology Display
Classification code:	PZZ
Regulation number:	21 CFR §864.3700

Predicate device

MMPC-4227F1 (PP27QHD), Display used in Philips Intellisite Pathology Solution, referenced in 510(k) - K192259 (Philips Intellisite Pathology Solution)

Device description

The Barco MDPC-8127 is a medical, color-calibrated display, specifically intended for review and interpretation of surgical pathology slides from IVD-labeled whole-slide imaging scanners and digital pathology image viewing software that have been validated for use with the display.

The use of the MDPC-8127 display with scanners and viewing software is determined by using verified test methods to establish the display's capability to meet or exceed the performance specifications and the intended color space specified by the IVD-labeled whole-slide imaging scanners and digital pathology image viewing software.

The display uses built-in techniques and technology to ensure constant accuracy over time.

The MDPC-8127 consists of an 8 mega-pixel, 27-inch color LCD-panel with internal electronics platform. It is calibrated to defined color spaces for whole-slide imaging and is compatible with digital pathology viewing software that utilizes defined color spaces to ensure images are displayed in intended colors.

The display is available with the following software accessories:

- Intuitive Workflow Tools (When paired with a Barco MXRT display controller graphics card and driver software)

Table 1: Relevant performance specifications with verified test methods

Test	Test Method	Results	
		MDPC-8127	**Predicate device**
User controls	Out-of-the-box settings	Luminance target, maximum: 450 cd/m^2 Display function: sRGB White point: 6500K Color space: sRGB 10 minutes of warm-up time	Luminance target, maximum: 350 cd/m2 Display function: sRGB White point: 6500K Color space: sRGB 10 minutes of warm-up time
Spatial resolution	Roehrig, Hans, et al. "In-field evaluation of the modulation transfer function of electronic display devices." *Medical Imaging 2004: Visualization, Image-Guided Procedures, and Display*. Vol. 5367. International Society for Optics and Photonics, 2004	Both horizontal and vertical MTFs are greater than 85% at Nyquist frequency	Both horizontal and vertical MTFs are greater than 75% at Nyquist frequency
Pixel defects	7.6 Defective Pixels, IDMS v1.03b	Total number of bright and dark pixels <= 5 with a minimum distance greater than 15 mm.	Total number of bright and dark pixels <= 3 within a circle of 10 mm. diameter
Artifacts	Image retention after 1 hour	< 0.65%	< 0.65%
Temporal response	10.2.3 Gray-to-Gray Response Time, IDMS v1.03b	The response time ranges from 3.1 ms to 6.2 ms with an average of 5.01 ms.	The response time is maximum 15 ms and typical 8 ms.
Maximum and minimum luminance	5 Fundamental Measurements, IDMS v1.03b	The maximum and minimum achievable luminance values are 678.6 and 0.633 cd/m^2, respectively. The calibrated luminance target is 450 cd/m^2. The contrast ratio is greater than 1000:1.	The maximum and minimum achievable luminance values are 550 and 0.3 cd/m2, respectively. The calibrated luminance target is 350 cd/m2. The contrast ratio is 1000:1.
Grayscale	Contrast response deviation, AAPM TG-18	Maximum error calculated = 1.4%	Maximum error calculated = 2.1%
Luminance uniformity and Mura test	8 Uniformity Measurements, IDMS v1.03b	<10% non-uniformity on 80% video level	21% non-uniformity on 80% video level

Stability of luminance and chromaticity response	Luminance and chromaticity characteristics of the display measured with temperature and time	Deviation from target luminance (450 cd/m^2): ±0.44% Variations for luminance and chromaticity: < 5% deviation	Deviation from target luminance (350 cd/m2): ±0.2% Variations for luminance and chromaticity: < 2% deviation
Bidirectional reflection distribution function	11. Reflection Measurements, IDMS v1.03b	Specular reflection coefficient: 1.90% Diffuse reflection coefficient: 2.87%	Specular reflection coefficient: 1.69% Diffuse reflection coefficient: 2.21%
Gray tracking	6.15 Gray-scale Color Changes, IDMS v1.03b	+/- 0.01 Δu'v' White point at D65: +/- 0.01 Δu'v'	+/- 0.002 Δu'v' White point at D65: +/- 0.002 Δu'v'
Color scale	6. Gray- and Color-Scale Measurement, IDMS v1.03b	Average color error < 1 ΔE_{00} Maximum color error < 3 ΔE_{00}	Average color error < 2 ΔE00 Maximum color error < 5 ΔE00
Color gamut volume	5.18.1 Relative Gamut Area, IDMS v1.03b	2D color gamut wrt sRGB: 137.1% 2D color gamut overlapped with sRGB: 99.6%	2D color gamut wrt sRGB: 99.4% 2D color gamut overlapped with sRGB: 98.4%

Intended Use

The Barco MDPC-8127 device is intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device. It is an aid to the pathologist to review and interpret digital images of histopathology slides for primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using the MDPC-8127. The display is not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.

Table 2: Comparison of technological characteristics

Item	Proposed Device MDPC-8127	Predicate device MMPC-4227F1 (PP27QHD)
Screen technology	IPS	Same
Active screen size (diagonal)	684 mm (27")	Same
Dimensions (W x H x D)	651 x 482~582 x 238 mm	648.5 x 473~573 x 235 mm
Resolution	8MP (3840 x 2160 pixels)	3.6MP (2560 x1440 pixels)
Color bit depth (internal)	10 bit color	8 bit color
Calibrated luminance	450 cd/m²	350 cd/m²
Contrast ratio	1000:1	1000:1
Uniformity Technology	Color PPU	None
Color Calibration	sRGB and DICOM GSDF modes	sRGB and DICOM GSDF modes
Front sensor for stabilization and calibration	Yes, I-Guard™	Front sensor

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Performance testing

According to FDA Guidance document titled “Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: April 20, 2016” (TPA Guidance), Chapter IV (A) (11), the below-mentioned tests were performed on the proposed device and the predicate device to verify that the technical characteristics and performance of the proposed display are equivalent to the predicate device:

- Spatial Resolution
- Pixel defects
- Artefacts
- Temporal response
- Max and Min Luminance
- Grayscale
- Luminance Uniformity and Mura Test
- Stability of Luminance and Chromaticity with Temperature and Lifetime
- Bidirectional Reflection Distribution
- Chromaticity and Gray Tracking
- Color Scale
- Color Gamut Volume

Other non-clinical tests were performed on the proposed device to demonstrate that the proposed device complies with the following international and FDA-recognized standards:

- IEC 60601-1:2005 Edition 3 + A1:2012 (Electrical safety)
- ANSI AAMI 60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (Electrical safety)
- IEC 60601-1-2:2014 (EMC)
- IEC 62304:2006 / A1:2015 (Software lifecycle process)

Finally, to test the performance of the proposed device in use with its software accessories, System Integration tests have been performed.

The non-clinical bench tests have demonstrated that the proposed device has equivalent or higher performance and technical characteristics compared to the predicate device and performs according to the requirements for displays used in Digital Pathology Whole Slide Imaging Devices following the corresponding TPA guidance and display requirements from FDA cleared IVD-labeled whole-slide imaging scanners and/or digital pathology image viewing software platforms.

Additional bench tests have demonstrated that the proposed device complies with applicable international and FDA-recognized standards and can be used safely with its software accessories.

Conclusion

The proposed device MDPC-8127 is substantially equivalent with the predicate device in terms of intended use, technological characteristics, performance, safety and effectiveness.

Non-clinical tests according to the TPA guidance have been performed to assess the technical characteristics of the display for its intended use and have demonstrated that the MDPC-8127 has equivalent or better

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performance than the other devices under test; as well as compatible with FDA cleared IVD-labeled whole-slide imaging scanners and/or digital pathology image viewing software platforms.

The tests have demonstrated that the proposed device is as safe and effective as the predicate device. Additionally, it has been demonstrated that the proposed device may be used for primary diagnosis in the following validated FDA-cleared WSI systems and digital pathology viewing software:

- Philips Intellisite Pathology Solution with Philips Image Management System viewing software, cleared under K192259
- Philips Intellisite Pathology Solution with Paige.AI Inc. FullFocus DX viewing software, cleared under K201005
- Leica Aperio AT2 DX System with ImageScope DX viewing software, cleared under K190332
- Leica Aperio AT2 DX scanner with Sectra Digital Pathology Module, cleared under K193054