Barco NV
% Ms. Julie Vandecandelaere
Regulatory Affairs Officer
President Kennedypark 35
8500 Kortrijk W-VL
BELGIUM

September 6, 2019

Re: K191845
Trade/Device Name: Coronis Fusion 6MP - MDCC-6530, Coronis Fusion 4MP - MDCC-4430, Intuitive Workflow Tools (IWT)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: July 5, 2019
Received: July 10, 2019

Dear Ms. 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
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)*

K191845

Device Name
MDCC-6530
MDCC-4430
Intuitive Workflow Tools (IWT)

Indications for Use *(Describe)*

The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis 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.

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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)*

Device Name
MDCC-4430

Indications for Use *(Describe)*
The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis 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)

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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)*

Device Name
Intuitive Workflow Tools

Indications for Use *(Describe)*
The Intuitive Workflow Tools are intended to be used as accessories for image enhancement in diagnostic displays.

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)

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510(k) Summary (in accordance with 21 CFR 807.92)	K191845
1. Company	Barco N.V. Healthcare Division 35 President Kennedypark B-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	05 July 2019
4. Device information	Trade name/model: Coronis Fusion 6MP (MDCC-6530) Coronis Fusion 4MP (MDCC-4430) Intuitive Workflow Tools (IWT) Common name: MDCC-6530 MDCC-4430 Intuitive Workflow Tools (IWT) Classification name: System, image processing, Radiological Classification code: PGY Regulation number: 892.2050
5. Predicate device	Coronis Fusion 6MP (MDCC-6230) cleared under 510(K) K130103
6. Device description	The MDCC-6530 is a derivative of the MDCC-6230. ✓ Updated Liquid Crystal Display technology, providing a higher Contrast Ratio ✓ New housing, display stand and internal mechanics ✓ Change in electronics board, including integration of the power supply adaptor into the device ✓ Updated firmware ✓ New packaging

<table>
<tr><td></td><td>The MDCC-4430 only differs from MDCC-6530 in having a 4MP panel instead of a 6MP panel.

The Intuitive Workflow Tools package includes some software tools that are intended to support the intended use of the diagnostic displays by performing image enhancement.</td></tr>
<tr><td>7. Intended Use of the Device</td><td>The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

Note: There are no changes to the indications for use statement from that of the unmodified device.

The Intuitive Workflow Tools are intended to be used as accessories for image enhancement in diagnostic displays.</td></tr>
<tr><td>8. Comparison of technological characteristics</td><td>
<table>
<tr><th>Item</th><th>Predicate Device (K130103)</th><th>Device for which listing is sought</th><th>Device for which listing is sought</th></tr>
<tr><td>Device name</td><td>Coronis Fusion 6MP (MDCC-6230)</td><td>Coronis Fusion 6MP (MDCC-6530)</td><td>Coronis Fusion 4MP (MDCC-4430)</td></tr>
<tr><td>Screen technology</td><td>TFT AM Color LCD Dual Domain IPS-Pro</td><td>IPS</td><td>IPS</td></tr>
<tr><td>Active screen size (diagonal)</td><td>772 mm (30.4")</td><td>772 mm (30.4")</td><td>772 mm (30.4")</td></tr>
<tr><td>Active screen size (HxV)</td><td>654 x 409 mm (25.8 x 16.1")</td><td>654 x 409 mm (25.8 x 16.1")</td><td>655 x 410 mm (25.8 x 16.1")</td></tr>
<tr><td>Aspect ratio (H:V)</td><td>16:10</td><td>16:10</td><td>16:10</td></tr>
<tr><td>Resolution</td><td>Native 6MP (3280 x 2048 pixels)
Configurable to 2 x 3MP+ (1640 x 2048 pixels)
Configurable to 2 x 3MP (1536 x 2048 pixels)</td><td>Native 6MP (3280 x 2048 pixels)
Configurable to 2 x 3MP+ (1640 x 2048 pixels)
Configurable to 2 x 3MP (1536 x 2048 pixels)</td><td>Native 4MP (2560 x 1600 pixels)
Configurable to 2 x 2MP+ (1280 x 1600 pixels)
Configurable to 2 x 2MP (1200 x 1600 pixels)</td></tr>
<tr><td>Pixel pitch</td><td>0.1995 mm</td><td>0.1995 mm</td><td>0.256 mm</td></tr>
<tr><td>Color imaging</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Gray imaging</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Bit depth</td><td>30 bit</td><td>30 bit</td><td>30 bit</td></tr>
<tr><td>Viewing angle (H, V)</td><td>178°</td><td>178°</td><td>178°</td></tr>
<tr><td>Uniformity Correction</td><td>ULT</td><td>ULT - Color PPU</td><td>ULT - Color PPU</td></tr>
<tr><td>Ambient Light Presets</td><td>Yes, reading room selection</td><td>Yes, reading room selection</td><td>Yes, reading room selection</td></tr>
<tr><td>Ambient Light Sensor</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Front sensor</td><td>Yes, I-Guard (Coronis)</td><td>Yes, I-Guard (Coronis)</td><td>Yes, I-Guard (Coronis)</td></tr>
</table>
</td></tr>
</table>

Maximum luminance (panel typical)	720 Cd/m²	1050 Cd/m²	1050 cd/m²
DICOM calibrated luminance	500 Cd/m²	600 Cd/m²	600 cd/m²
Contrast ratio (panel typical)	1000:1	2000:1	2000:1
Response time (panel typical data [1]) $T_{r,typ}$ $T_{f,typ}$	 9 ms 9 ms	 20 ms 16 ms	 20 ms 16 ms
Housing color	Black / Silver	Black / White	Black / White
Video input signals	DVI-D Dual Link (2x), DisplayPort (2x)	2 x DP1.2	2 x DP1.2
Video output signals	N/A	1 x DP (MST)	1 x DP (MST)
USB ports	1x USB 2.0 upstream (endpoint) 3x USB 2.0 downstream	1x USB 2.0 upstream (endpoint) 2x USB 2.0 downstream 1x USB 2.0 downstream with high-power charging functionality	1x USB 2.0 upstream (endpoint) 2x USB 2.0 downstream 1x USB 2.0 downstream with high-power charging functionality
Power rating	100-240V	100-240 Vac, 50/60 Hz, 3.6-1.6 A	100-240 Vac, 50/60 Hz, 3.6-1.6 A
Power consumption	125W	110 W (nominal) @ calibrated luminance of 600 cd/m² < 0.5 W (hibernate) < 0.5 W (standby)	110 W (nominal) @ calibrated luminance of 600 cd/m² < 0.5 W (hibernate) < 0.5 W (standby)
Dimensions with stand (W x H x D)	731 x 580~676 x 265 mm	714 x 524~624 x 240 mm	714 x 524~624 x 240 mm
Dimensions without stand (W x H x D)	731 x 485 x 141 mm	714 x 478 x 74 mm	714 x 478 x 74 mm
Dimensions packaged (W x H x D)	869 x 764 x 400 mm	800 x 650 x 300 mm	800 x 650 x 300 mm
Net weight with stand	26.5 kg	17.7 kg	17.7 kg
Net weight without stand	20 kg	13.1 kg	13.1 kg
Net weight packaged	36.5 kg	22.3 kg (without optional accessories)	22.3 kg (without optional accessories)
Tilt	-5° to +25°	-5° to +25°	-5° to +25°
Swivel	-45° to +45°	-30° to +30°	-30° to +30°

	Pivot	N/A	N/A	N/A
	Height adjustment range	96 mm	100 mm	100 mm
	Mounting standard	VESA (100 mm)	VESA (100 mm)	VESA (100 mm)
	Screen protection	Protective, anti-reflective glass cover	Protective, anti-reflective glass cover	Protective, anti-reflective glass cover
	Recommended modalities	CT, MR, US, DR, CR, NM, Film	All digital images, except digital mammography.	All digital images, except digital mammography.
	Supplied accessories	User Guide Quick Installation Sheet Documentation disc System disc Video cables Mains cables USB cable External power supply	User Guide Documentation disc Video cables Mains cables USB cable	User Guide Documentation disc Video cables Mains cables USB cable
	Optional accessories	Graphics board	Graphics board Touch pad	Graphics board Touch pad
	QA software	QAWeb	QAWeb	QAWeb
	Warranty	5 years	5 years, including 40,000 hours backlight warranty	5 years, including 40,000 hours backlight warranty
	Operating temperature	0 °C to 35 °C (15 °C to 30 °C within specs)	0 °C to 35 °C (15 °C to 30 °C within specs)	0 °C to 35 °C (15 °C to 30 °C within specs)
	Storage temperature	-20 °C to 60 °C	-20 °C to 60 °C	-20 °C to 60 °C
	Operating humidity	8 % to 80 % (non-condensing)	20 % to 85 % (non-condensing)	20 % to 85 % (non-condensing)
	Storage humidity	5 % to 95 % (non-condensing)	20 % to 85 % (non-condensing)	20 % to 85 % (non-condensing)
	Minimum operating pressure	3000 m	70 kPa	70 kPa
	Storage pressure	N/A	50 to 106 kPa	50 to 106 kPa
	Note [1] Response time: the stated values are the values as specified in the datasheet of the LCD module by the LCD manufacturer and are defined as the transitions between black (0%) and white (100%) luminance value: More detailed measurement results for other luminance value transitions are available in the Bench Test Equivalence report.			
9. Performance testing	The bench tests mentioned below were performed to validate the device characteristics that differ from the predicate device:			

	Modification to device	**Test performed**	**Criteria**
	Update to the LCD panel, providing a higher Contrast Ratio and maximum output Luminance	Bench Test Equivalence report	PASS
	Change in housing and display stand	Environmental tests Electrical Safety tests EMC tests	PASS PASS PASS
	Change in internal mechanics	Environmental tests Electrical Safety tests EMC tests	PASS PASS PASS
	Change in electronics board	Environmental tests Electrical Safety tests EMC tests	PASS PASS PASS
	Updated firmware	Firmware tests	PASS
	Change in packaging	Environmental tests	PASS
	Internal power supply instead of external power supply	Electrical Safety tests	PASS
	The tests showed that the device has similar characteristics compared to the predicate device and did not reveal new issues of safety and performance. Animal testing has not been performed.		
10. Conclusion	The Coronis Fusion 6MP and 4MP were 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.		

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