DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 18, 2016

Barco N.V.
% Mr. Lieven De Wandel
Regulatory Officer
President Kennedypark 35
Kortrijk, 8500
BELGIUM

Re: K161229
Trade/Device Name: Mammo Tomosynthesis (MDMG-5221)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: April 25, 2016
Received: May 2, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161229

Device Name

Mammo Tomosynthesis (MDMG-5221)

Indications for Use *(Describe)*

The Barco Mammo Tomosynthesis (MDMG-5221) device is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners.

It is specially designed for breast tomosynthesis applications.

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

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary (in accordance with 21 CFR 807.92)

1. Company	Barco N.V. Healthcare Division 35 President Kennedypark B-8500 Kortrijk BELGIUM
2. Contact person	Lieven De Wandel Regulatory Affairs Officer
3. Date of submission	25 April 2016
4. Device information	Trade name/model: Mammo Tomosynthesis 5MP (MDMG-5221) Common name: MDMG-5221 Classification name: System, image processing, Radiological Classification code: LLZ Regulation number: 892.2050
5. Predicate device	Mammo Tomosynthesis 5MP (MDMG-5221) cleared under 510(K) K090603
6. Device description	MDMG-5221, system name Barco Mammo Tomosynthesis, is an update of the 5MP display, specifically addressing the requirements of the emerging modality of Digital Breast Tomosynthesis (DBT) and QA software. The display controller board is installed in a PACS workstation computer, connected to the display. The QA software helps to make and keep the displays DICOM compliant. The display uses LED backlight technology.
7. Intended Use of the Device	The Barco Mammo Tomosynthesis (MDMG-5221) device is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

8. Comparison of technological characteristics

Specification	MDMG-5221 (new device)	MDMG-5221 (predicate device)
Screen technology	TFT AMLCD Dual Domain IPS grayscale	TFT AMLCD Dual Domain IPS grayscale
Active screen size (diagonal)	540.9 mm (21.3”)	540.9 mm (21.3”)
Active screen size (H x V)	422.4 x 377.9 mm (16.6 x 13.3“)	422.4 x 377.9 mm (16.6 x 13.3“)
Aspect ratio (H:V)	4:5	4:5
Resolution	2048 x 2560	2048 x 2560
Pixel pitch	0.165 mm (0.0065”)	0.165 mm (0.0065”)
Color imaging	No	No
Gray imaging	Yes	Yes
Viewing angle (H, V)	176° (at 10:1 contrast)	176° (at 10:1 contrast)

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	Uniform Luminance Technology (ULT)	Yes	Yes
	Per Pixel Uniformity (PPU)	Yes	Yes
	Ambient Light Compensation (ALC)	Yes	Yes
	Backlight Output Stabilization (BLOS)	No	No
	I-Guard	Yes	Yes
	Maximum luminance	2100 cd/m²	2100 cd/m²
	DICOM calibrated luminance (ULT off)	1000 cd/m²	1000 cd/m²
	Contrast ratio (typical)	950:1	950:1
	Response time (Tr + Tf)	15 ms (typical)	15 ms (typical)
	Video input signals	DP, DVI	DP, DVI
	USB ports	1 upstream, 2 downstream	1 upstream, 2 downstream
	USB standard	2.0	2.0
	Power consumption (nominal)	125W	125W
	Power save mode	Yes	Yes
	Net weight with stand	15.4 kg	15.4 kg
	Net weight w/o stand	10.9 kg	10.9 kg

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**
LED backlight instead of CCFL	DICOM calibration and Luminance Uniformity tests
Updated firmware	Firmware tests

Additional tests performed: Electrical Safety test (IEC 60601-1), EMC test (IEC 60601-1-2)

The tests showed that the device has similar or superior characteristics compared to the predicate device and did not reveal new issues of safety and performance.

Animal or clinical testing have not been performed.

10. Conclusion

The Mammo Tomosynthesis (MDMG-5221) 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 or superior characteristics compared to the predicate device and did not reveal new issues of safety and performance.

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