February 22, 2018

Barco n.v.
Eric Caus
Regulatory Affairs Officer
Beneluxpark 21
B-8500 Kortrijk
Belgium

Re: K173381
Trade/Device Name: Nexxis OR
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: January 29, 2018
Received: January 29, 2018

Dear Eric Caus:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K173381

Device Name
Nexxis OR

Indications for Use *(Describe)*
The Barco Nexxis OR system is designed to allow transfer, selection and distribution of A/V signals and medical images from various commercially available instruments that are commonly used in a medical procedure laboratory or operating room.
The Barco Nexxis OR system is also designed for transfer, selection and distribution of human interface signals and control signals of non-medical room equipment,
The Barco Nexxis OR system allows control and selection of these signals from a central point.
The Barco Nexxis OR system is not intended to be used for remote or robotically assisted surgery,
The Barco Nexxis OR system is not intended to be used in the vicinity of MRI or other devices that use strong magnetic fields.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (in accordance with 21 CFR 807.92)	
1. Company	Barco N.V. Healthcare Division 35 President Kennedy park B-8500 Kortrijk BELGIUM
2. Contact person	Eric Caus Regulatory Affairs Officer
3. Date of submission	25 October 2017
4. Device information	Trade name/model: Nexxis OR Common name: Nexxis Classification name: Cathode-Ray Tube, Medical Classification code: DXJ Class: II Regulation number: 870.2450
5. Predicate devices	Nexxis OR cleared under K170537 (and K122167 before).
6. Device description	The Nexxis OR system is a solution for video distribution in operating rooms and medical procedure laboratories. The Nexxis OR can consist of any possible combination of the Nexxis encoders/decoders that transfer video signals from various available devices to one or more output devices (displays). Additionally the Nexxis components can transfer audio signals and USB signals. The USB communication is intended only for keyboard and mouse control and control signals for non-medical room equipment. The selection of sources and output devices is done by control software (NMS API). The Nexxis OR system can also contain, optionally, the MNC-180 compositor device, a MDSC-8258 MNA display and/or the touch user interface MUIP-2112. The Nexxis OR system may now consist of any combination of the following components: a) Nexxis OR components (Medical network adaptors) b) Nexxis Compositor with NCS composition software (MNC-180) c) Nexxis Management Suite (NMS). d) A 58-inch large screen LCD monitor: Barco MDSC-8258 MNA.(optional) e) touch user interface MUIP-2112 (optional) f) Cables g) Documentation

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<table>
<tr><td>7. Intended Use/Indications for Use</td><td>The Barco Nexxis OR system is designed to allow transfer, selection and distribution of A/V signals and medical images from various commercially available instruments that are commonly used in a medical procedure laboratory or operating room.
The Barco Nexxis OR system is also designed for transfer, selection and distribution of human interface signals and control signals of non-medical room equipment,
The Barco Nexxis OR system allows control and selection of these signals from a central point.
The Barco Nexxis OR system is not intended to be used for remote or robotically assisted surgery,
The Barco Nexxis OR system is not intended to be used in the vicinity of MRI or other devices that use strong magnetic fields.

This is the same as the predicate device Nexxis OR cleared under K170537.</td></tr>
<tr><td>8. Comparison of technological characteristics</td><td>
<table>
<tr><th>Product acronym</th><th>Nexxis OR</th><th>Nexxis OR (K170537)</th></tr>
<tr><td>Distribution/Switching of video signals and network connection</td><td>• Any combination of Nexxis OR components.
• Barco Nexxis management software (NMS) and API.
• Network Switches (optional)</td><td>• Any combination of Nexxis OR components.
• Barco Nexxis management software (NMS) and API
• Network Switches (optional)</td></tr>
<tr><td>Display</td><td>MDSC-8258 MNA (option)</td><td>MDSC-8258 MNA (option)</td></tr>
<tr><td>Tablet PC (control unit)</td><td>Optional tablet MUIP-2112</td><td>No tablet</td></tr>
<tr><td>Composition of video image</td><td>Barco updated MNC-180 (up to 8 uncompressed video streams combining into a single 4k image in IP format.</td><td>Barco MNC-180 (up to 8 uncompressed video streams combining into a single 4k image in IP format.</td></tr>
<tr><td>Graphical User Interface</td><td>Graphical user interface, Nexxis OR GUI.</td><td>No graphical user interface</td></tr>
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</td></tr>
<tr><td>9. Performance testing</td><td>Summary tests that were performed to validate the device:

- Display bench tests
- Display validation tests
- Nexxis OR qualification tests
- System tests

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

Animal or clinical testing have not been performed.</td></tr>
<tr><td>10. Conclusion</td><td>The Nexxis OR has been 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 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.</td></tr>
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