



April 21, 2017

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

Barco N.V.
Eric Caus
Regulatory Affairs Officer
Beneluxpark 21
Kortrijk, 8500 BE

Re: K170537
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: March 17, 2017
Received: March 17, 2017

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.

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,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170537

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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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	20 February 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	SIVR56-T kit cleared under 510(K) K133994 Nexxis OR cleared under K122167. This is the primary predicate device.
6. Device description	<p>The generic Nexxis OR system is a solution for video distribution in operating rooms and medical procedure laboratories. The generic 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).</p> <p>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.</p> <p>The selection of sources and output devices is done by control software (NMS API).</p> <p>The generic Nexxis OR system can also contain, optionally, the MNC-180 compositor device and/or a MDSC-8258 MNA display.</p> <p>The Nexxis OR system may consist of any combination of the following components:</p> <ul style="list-style-type: none"> a) Nexxis OR components (MNA adapters (encoders and decoders), NMS management SW, network switches, SFP+ modules) b) A 58-inch large screen LCD monitor: Barco MDSC-8258 MNA. (optional) c) Nexxis Compositor (MNC-180) (optional) d) Cables e) Documentation

<p>7. Intended Use/Indications for Use</p>	<p>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.</p> <p>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.</p> <p>The Barco Nexxis OR system is not intended to be used for remote or robotically assisted surgery,</p> <p>The Barco Nexxis OR system is not intended to be used in the vicinity of MRI or other devices that use strong magnetic fields.</p> <p>This is the same as the predicate device Nexxis OR cleared under K122167</p>																											
<p>8. Comparison of technological characteristics</p>	<table border="1"> <thead> <tr> <th data-bbox="381 646 678 709">Product acronym</th> <th data-bbox="678 646 948 709">Nexxis OR</th> <th data-bbox="948 646 1203 709">First Nexxis OR (K122167)</th> <th data-bbox="1203 646 1463 709">SIVR56-T kit</th> </tr> </thead> <tbody> <tr> <td data-bbox="381 709 678 1081">Distribution/Switching of video signals and network connection</td> <td data-bbox="678 709 948 1081"> <ul style="list-style-type: none"> Any combination of Nexxis OR components. Barco Nexxis management software (NMS) and API Network Switches (optional) </td> <td data-bbox="948 709 1203 1081"> <ul style="list-style-type: none"> Any combination of Nexxis OR components. Barco Nexxis management software (NMS) and API Network Switches (optional) </td> <td data-bbox="1203 709 1463 1081"> <ul style="list-style-type: none"> Customer defined combination of Nexxis OR components. Barco Nexxis management software (NMS) and API Network Switches </td> </tr> <tr> <td data-bbox="381 1081 678 1144">Display</td> <td data-bbox="678 1081 948 1144">MDSC-8258 MNA (option)</td> <td data-bbox="948 1081 1203 1144">No display included</td> <td data-bbox="1203 1081 1463 1144">MDSC-8156</td> </tr> <tr> <td data-bbox="381 1144 678 1207">Tablet PC (control unit)</td> <td data-bbox="678 1144 948 1207">No tablet, no GUI</td> <td data-bbox="948 1144 1203 1207">No tablet, no GUI</td> <td data-bbox="1203 1144 1463 1207">MTPP-0212 XSBM with GUI</td> </tr> <tr> <td data-bbox="381 1207 678 1423">Composition of video image</td> <td data-bbox="678 1207 948 1423">Barco MNC-180 (up to 8 uncompressed video streams combining into a single 4k image in IP format.</td> <td data-bbox="948 1207 1203 1423">No composition of images</td> <td data-bbox="1203 1207 1463 1423">SuperView 4K compositor (composes up to 8 video inputs to 1 composition up to 4K DVI video output)</td> </tr> <tr> <td data-bbox="381 1423 678 1486">Graphical User Interface</td> <td data-bbox="678 1423 948 1486">No graphical user interface</td> <td data-bbox="948 1423 1203 1486">No graphical user interface</td> <td data-bbox="1203 1423 1463 1486">Third party application</td> </tr> </tbody> </table>				Product acronym	Nexxis OR	First Nexxis OR (K122167)	SIVR56-T kit	Distribution/Switching of video signals and network connection	<ul style="list-style-type: none"> Any combination of Nexxis OR components. Barco Nexxis management software (NMS) and API Network Switches (optional) 	<ul style="list-style-type: none"> Any combination of Nexxis OR components. Barco Nexxis management software (NMS) and API Network Switches (optional) 	<ul style="list-style-type: none"> Customer defined combination of Nexxis OR components. Barco Nexxis management software (NMS) and API Network Switches 	Display	MDSC-8258 MNA (option)	No display included	MDSC-8156	Tablet PC (control unit)	No tablet, no GUI	No tablet, no GUI	MTPP-0212 XSBM with GUI	Composition of video image	Barco MNC-180 (up to 8 uncompressed video streams combining into a single 4k image in IP format.	No composition of images	SuperView 4K compositor (composes up to 8 video inputs to 1 composition up to 4K DVI video output)	Graphical User Interface	No graphical user interface	No graphical user interface	Third party application
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<p>9. Performance testing</p>	<p>Summary of bench tests that were performed to validate the device:</p> <ul style="list-style-type: none"> - Display bench tests - Display validation tests - Nexxis OR qualification tests - System tests <p>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 effectiveness.</p> <p>Animal or clinical testing have not been performed.</p>																											

10. Conclusion	<p>The Nexxis OR has been found to be substantially equivalent to the predicate device, due to the following reasons:</p> <ul style="list-style-type: none">a) Device and predicate device have the same intended useb) The technological differences from the predicate device do not affect safety or effectivenessc) 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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