



September 30, 2026

Barco N.V.
Eric Caus
Regulatory Officer
President Kennedypark 35
Kortrijk, 8500
Belgium

Re: K261469

Trade/Device Name: Nexxis 2;Nexxis OR 2;NMS 2;MNA-240;MNA-4x0 (Where "x" may be any numeric character).

Regulation Number: 21 CFR 870.2450

Regulation Name: Medical Cathode-Ray Tube Display

Regulatory Class: Class II

Product Code: DXJ

Dated: August 31, 2026

Received: August 31, 2026

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K.
Chen -S

Digitally signed by
Colin K. Chen -S
Date: 2026.09.30
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Colin Kejing Chen, Ph.D.
Assistant Director
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Enclosure

Indications for Use

510(k) Number (if known)

K261469

Device Name

Nexxis 2;

Nexxis OR 2;

NMS 2; MNA-240; MNA-4x0 (where "x" can be any number); NexxisOR 2

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) #:

510(k) Summary

Prepared on: 2026-09-30

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Barco nv
Applicant Address	President Kennedypark 35 Kortrijk 8500 Belgium
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Applicant Contact	Mr. Eric Caus
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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Nexxis 2; Nexxis OR 2; NMS 2; MNA-240; MNA-4x0; NexxisOR 2
Common Name	Medical cathode-ray tube display
Classification Name	Display, Cathode-Ray Tube, Medical
Regulation Number	870.2450
Product Code(s)	DXJ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173381	Nexxis OR, Nexxis, NMS, MNA-110, MNA-120, MNA-240	DXJ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Nexxis OR 2.x is Barco's next-gen video-over-IP platform for the integrated digital operating room. Nexxis OR 2.x is a solution for video distribution in operating rooms and medical procedure laboratories. It transfers signals from various available devices to one or more output devices.

Additionally it 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 outputs is done by control software, Nexxis Management Suite (NMS), which is presented as application programming interface (API) or the Nexxis Graphical User Interface (Nexxis 2.x UI). The end-user interface, Nexxis 2 UI, is an optional part of the system, or the customer (integrator) can use their own user interface.

In the Nexxis OR 2.x solution the various signals are transferred in uncompressed way via the network in IP format. Encoders connected to the source devices convert the available signals to IP streams, whereas decoders, connected to the output devices, convert the IP streams back to video, audio and USB signals. This conversion is achieved with near-zero latency and maintains high signal quality.

The Nexxis OR 2.x system consists of the following components:

- * Nexxis MNA (Medical Network Adapter) interfaces for encoding and decoding. The interfaces may vary in the video formats they support.
- * Nexxis management suite (NMS 2.x) including:

- an API and graphical user interface (Nexxis 2.x UI). NMS can also be accessed by the customer's application software through its API
- Nexxis workspot, a control room solution for interventional surgery brings together all imaging sources on a single display, managed by a single keyboard and mouse.
- * Nexxis Network Switch(es) for distribution of video, audio and data (not medical devices, general ITE)
- * MNA-1x0 PCIe network cards (component, not medical device)
- * Small Form Factor Pluggable (SFP+) laser transceiver(s)
- * Cables: Power cables, video cables, optical fiber cables

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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.

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Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Technological characteristics of Nexxis 2 in comparison with Nexxis OR

The modifications are:

- Updated Network Management Suite Software
 - New programming language for NMS 2.x, all drivers have been updated
 - Communication between Nexxis devices has been updated, new OS for NMS 2.x
 - State-of-the-art security framework, embedded cybersecurity architecture
 - ☑ Secure authentication for devices & access control for users
 - ☑ End-to-end encryption for video and data streams
 - ☑ Firmware & boot security
 - ☑ Attack surface reduction
 - ☑ Logging & accountability
- New devices support:
 - Addition of MNA-4x0 network adapters
 - Support of new network switches
 - ☑ New generation of Extreme switches 5120
 - ☑ Netgear M4350 line
- Drop of support of MNA-1x0 (except MNA-1x0 PCIe), MNC-180 and MNT-120 devices
- New features: Color keying, 3D support, audio mixing, diagnostics, Zooming and cropping, RS-232 support, Streamback
- Major changes in functionality:
 - New API for NMS, based on GraphQL
 - New NMS licenses needed compared to Nexxis 1.xx
 - Nexxis 2 UI now supports multiple languages
 - Workspot support on MNA-440
 - Secure plug and play devices, device activation is needed before new devices can be used
 - Added support for Rocky Linux (NMS only)

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

To verify safety and effectiveness of these modifications and compliance to the referenced standards, we have conducted the following verification/validation activities, of which the reports are included in the submission:

- Nexxis 2.x system functional and non-functional verifications
- Nexxis 2.x system design validation proving that Nexxis OR 2.x fulfils its use requirements

- Risk management activities were performed and documented in accordance with the applicable risk management procedures according ISO 14971 Third Edition 2019-12
- Usability engineering according IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- Cybersecurity and data protection activities performed:
 - o Threat modeling, security Risk assessment, Privacy management (GDPR)
 - o S-BOM analysis
 - o Security testing
 - o Vulnerability management
 - o Third-party penetration testing
 - o Incident response management
- On hardware device level
 - o Electrical Safety tests according IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
 - o EMC tests according 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
 - o Environmental tests

The tests showed that the Nexxis 2.x has similar characteristics compared to already cleared device Nexxis OR and did not reveal new issues of safety and performance.

The Nexxis 2.x hardware devices are compliant to EMC and Safety standards, the environmental tests (climate, mechanical and packed) and software tests all passed.

As a conclusion we can state that the device Nexxis 2.x is found to be substantially equivalent to the predicate device Nexxis OR, because:

- The indications for use are the same as the predicate device
- The technological characteristics discussed above do not raise questions of safety and effectiveness
- The bench tests show that the Nexxis 2 characteristics are equivalent to those of the predicate device