December 13, 2024

Barco NV
Julie Vandecandelaere
Regulatory Affairs Officer
President Kennedypark 35
Kortrijk, 8500
Belgium

Re: K243307
Trade/Device Name: LCD Monitor (MDEC-2523)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 21, 2024
Received: October 21, 2024

Dear Julie 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 (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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.12.13 21:42:53 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243307

Device Name

LCD Monitor (MDEC-2523)

Indications for Use *(Describe)*

The device is intended to display medical images from endoscopic or laparoscopic camera systems and other compatible medical image systems.
The device is a medical grade monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, doctor's offices, clinics and similar medical environments.

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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510(k) #:

510(k) Summary

Prepared on: 2024-10-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Barco NV
Applicant Address	President Kennedypark 35 Kortrijk 8500 Belgium
Applicant Contact Telephone	+32 497 377770
Applicant Contact	Ms. Julie Vandecandelaere
Applicant Contact Email	julie.vandecandelaere@barco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	LCD Monitor (MDEC-2523)
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220069	4K UHD LCD Monitor OEV321UH	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

The MDEC-2523 is a medical grade monitor with a 23,8 inch color TFT-LDC screen size and is intended to display medical images from endoscopic or laparoscopic camera systems and other compatible medical image systems.

The MDEC-2523 consists of an LCD panel and LED backlight integrated into a plastic housing body with an internal metal chassis structure, that also integrates the electronics, sensors, and interconnections. The MDEC-2523 encloses user controls that are used to control and configure the device via the embedded on screen display (OSD) software. The device has a glass cover to protect the LCD panel and allow easy cleaning. The MDEC-2523 is powered by means of an internal power supply.

This monitor displays color video images that are output from medical imaging systems on the LCD (liquid crystal display) panel.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is intended to display medical images from endoscopic or laparoscopic camera systems and other compatible medical image systems.
The device is a medical grade monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, doctor's offices, clinics and similar medical environments.

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)

The principles of operation and the fundamental technology of the MDEC-2523 are identical to the predicate device. The differences in system parameters and specifications include device dimensions, input and output signals, active screen size, timings and resolution, luminance, gamma curve and color space. These differences do not raise new or different questions with respect to safety and effectiveness.
As the electrical safety and electromagnetic compatibility test results demonstrate equivalent performance, we believe there are no new concerns or modified existing risks regarding safety and effectiveness of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance testing was conducted to support the substantial equivalence determination:
- Electrical safety testing in accordance with ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- EMC testing in accordance with IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
- Environmental testing (Climate, shock and vibration, packed, thermal analysis)
- Software testing

MDEC-2523 is compliant to EMC and safety standards and the environmental and software tests passed.

Additionally, usability/human factors was conducted.

Clinical study -Not Applicable

As a conclusion we can state that the device MDEC-2523 is found to be substantially equivalent to the predicate device 4K UHD LCD Monitor OEV321UH and no new questions of safety or effectiveness are raised.