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

March 14, 2017

Barco N.V.
% Lieven Wandel
Regulatory Affairs Officer
Barco N.V.
35 President Kennedypark
Kortrijk, 8500 BE

Re: K161880
Trade/Device Name: NIVR58-T Kit
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: February 13, 2017
Received: February 13, 2017

Dear Lieven 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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K161880

Device Name

NIVR58-T kit

Indications for Use *(Describe)*

The kit is intended to be used by healthcare professionals to integrate the video from various commercially available instruments commonly used in a medical procedure into a single video display.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Paperwork Reduction Act (PRA) Staff
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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 Kennedypark B-8500 Kortrijk BELGIUM
2. Contact person	Lieven De Wandel Regulatory Affairs Officer
3. Date of submission	05 July 2016
4. Device information	Trade name/model: NIVR58-T kit Common name: - Classification name: Cathode-Ray Tube, Medical Classification code: DXJ Regulation number: 870.2450
5. Predicate device	SIVR56-T, cleared under 510(K) K133994
6. Device description	The NIVR58-T kit is a set of devices bundled together by Barco as a system, to be used in a larger system of a customer. The system that Barco composes, consists of the following devices: a) A 58-inch large screen LCD monitor: Barco **MDSC-8258 MNA**. b) Nexxis Compositor (**MNC-180**) **c) Nexxis OR components** d) A control unit panel PC (tablet PC): Barco **MTPP-0212** (other name: Proscribe) with control user interface. e) Cables f) Documentation The NIVR58-T kit is the visualization part in an operating room or cathlab. The video sources from different medical devices in the OR are connected to the NIVR58-T kit. The NIVR58-T kit makes a composition of the video signals and sends the composition signals to the 58-inch display. The selection of the video sources that have to be displayed and the layout of the composition is done by the Nexxis OR component and controlled by the control unit MTTP 0212, on which a Graphical User Interface is installed.

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<table>
<tr><td>7. Intended Use of the Device</td><td>The NIVR58-T kit is intended to be used by healthcare professionals to integrate the video from various commercially available instruments commonly used in a medical procedure into a single video display.</td></tr>
<tr><td>8. Comparison of technological characteristics</td><td>
<table>
<tr><th>Product acronym</th><th>SIVR56-T kit</th><th>NIVR58-T kit</th></tr>
<tr><td>Display</td><td>MDSC-8156</td><td>MDSC-8258 MNA</td></tr>
<tr><td>Tablet PC (control unit)</td><td>MTPP-0212 XSBM</td><td>MTPP-0212 XSBM</td></tr>
<tr><td>Distribution/Switching of video signals and network connection</td><td>Nexxis OR</td><td>Nexxis OR</td></tr>
<tr><td>Composition of video image</td><td>SuperView 4K</td><td>Nexxis Compositor MNC-180</td></tr>
<tr><td>Graphical User Interface</td><td>Third party application</td><td>Factory-installed on MTTP</td></tr>
</table>
</td></tr>
<tr><td>9. Performance testing</td><td>Summary of bench 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 or superior 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 NIVR58-T kit 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 or superior characteristics compared to the predicate device and did not reveal new issues of safety and performance.</td></tr>
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