VIA UPS

June 7, 2017

Patrick Santy
BARCO N.V.
Beneluxpark 21
8500 Kortrijk, Belgium

Re: FDA Docket Number: 2016-V-0144-001
Accession Number: 16A0082-002

Dear Patrick Santy:

CDRH is approving, in accordance with 21 CFR 1010.4(c)(1), the petition of BARCO N.V. ("the firm") dated February 28, 2017, for a variance from 21 CFR 1040.11(c) of the performance standard for laser products.

This variance allows the introduction into commerce of the firm's family of laser illuminated digital image projectors (LIPs) for temporary and permanent show installations as described in paragraph D below.

A. Variance Number

2016-V-0144

B. Effective Date

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. Termination Date

This variance shall be terminated five (5) years from the date of this letter.

D. Product for Which Variance is Granted

This variance is granted for the Laser Class 1, Risk Group 3 UDX family of laser illuminated digital image projectors, models UDX 4K32, UDX 4K30, UDX 4K22, UDX 4K20, UDX W32, UDX W22, UDX W20, UDX U30, and UDX U22 produced by Barco N.V. These products are designed for front or rear screen image projections in permanent or temporary show installations other than cinema theatres in accordance with the conditions of this variance, and they are not designed or intended for home use.

E. Provisions From Which Variance is Granted

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products which requires that each demonstration laser product shall comply with all of the at applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

All other provisions of the applicable performance standard(s) remain applicable to the product.

F. Conditions Under Which Variance is Granted

In lieu of the requirement(s) referred to in Item E above, the conditions as specified below in Variance Attachment A shall apply to the products and devices manufactured under this variance and to the shows assembled and produced under this variance.

G. Basis for Approval of Variance

In accordance with 21 CFR 1010.4(a)(2)(iii), one or more requirements in Item E of the laser performance standard are not appropriate for the laser product. Suitable means for assuring radiation safety or protection will be provided by the constraints placed on the physical and optical design, warnings in the user/purchaser information, prescribed installation instructions, and limitations on the sale of laser product.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

> This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 2016-V-0144 effective on June 7, 2017.

This variance action is available for public disclosure in the Division of Dockets Management, Food and Drug Administration, and a notice of availability will be published in the FEDERAL REGISTER. The variance will remain in effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Should you have any questions or comments pertaining to this letter, please contact Woody Strzelecki by email at woody.strzelecki@fda.hhs.gov or by telephone at (301) 796-6939. In any follow-up correspondence, please clearly reference FDA Variance Number 2016-V-0144 and include your contact email address.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Cc'
Jan Daem
BARCO N.V.
jan.daem@barco.com

1. This variance is not transferable to any other firm or person and applies only to the specific products identified in the variance.

2. Classification shall be based on measurements of all the light emitted from the projection lens (projection light) in accordance with Section IV(a)(i) of the LIP guidance "Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIP)," (the LIP Guidance).

3. Permanent show installations and LIPs shall be certified to comply with applicable requirements of 21 CFR 1040.10 and, when determined to meet Section III, Scope of the LIP Guidance, with the requirements of Section IV Policy of the LIP Guidance, and with the conditions of this variance. They shall be reported as required by 21 CFR 1002.10 and 1002.11 using the reporting guides provided for such purpose. These actions shall be accomplished prior to any introduction into commerce.

4. Changes to the LIPs or the show installation instructions that affect the properties of the projection light or the manner of compliance shall be reported in a supplemental report as required by 21 CFR 1002.12 and in accordance with Conditions A.2 and A.3 of this variance. The submission of any supplements shall be done prior to any introduction into commerce.

5. Effects other than front or rear screen projections shall not be performed. Any additional effects require the submission of an amendment request (in accordance with 21 CFR 1010.4) and the filing of product reports or supplements as applicable.

6. A Hazard Zone is the region of space where the projection light from the LIP is above Emission Limits for RG2. RG3 LIPs for installations other than in cinema theaters shall be installed at a height vertically above the floor such that the bottom plane of the Hazard Zone shall be no lower than 3 meters above the floor. Horizontal clearance to the hazard zone shall be 2.5 meters. Any human access horizontally to the Hazard Zone, if applicable, shall be restricted by barriers. If human access is possible in an unsupervised environment, the horizontal or vertical clearances shall be increased to prevent exposure to the RG3 hazard zone.

7. Permanent show installations containing RG3 LIPs as described in the Paragraph D shall be installed by the firm or by firm-authorized and trained installers. Show installations must be performed in accordance with the firm's instructions. The projection system shall be securely mounted or immobilized to prevent unintended movement or misalignment of the projections.

8. Temporary show installations containing RG3 LIPs as described in Paragraph D may be installed by the firm or sold or leased only to valid laser light show variance holders (laser light show manufacturers) for image projection applications. Such manufacturers may currently hold a valid variance for production of Class IIIb and IV

laser light shows and/or for incorporation of the RG3 LIPs into their shows. This requirement applies also dealers and distributors of these LIPs.

For firm-installed show installations including customer or trade show demonstrations, the firm shall assure that:

a. The LIPs are located so that all propagating beam paths within the Hazard Zone, and the audience can be directly observed at all times;

b. Communication be maintained with other personnel assisting in surveillance of the LIP projection;

c. In the event of any unsafe condition, immediately terminates (or designate the termination) of LIP projection light;

d. Provide one or more readily accessible controls to immediately terminate LIP projection light.

9. The LIP must have labels indicating “No direct exposure to beam shall be permitted” and “Not for household use”.

10. The user information must include installation instructions that provide directions specifying that the LIP must be mounted high enough to provide the clearances required by Condition A.6 for people who may walk beneath the beam path or that a restricted access area which extends beyond the beam hazard distance must be established.

11. In addition to the requirements of 21 CFR 1040.10(h), the firm shall provide to purchasers who purchase or lease the equipment, adequate user's instructions for safe installation and operation. These instructions shall specify the required installation configurations and constraints needed to meet the conditions of this variance, specifically the minimum clearance distances specified by Condition A.6 of this variance.

    The requirements of 21 CFR 1002.30(a)(1) and (2) shall be accomplished through the use of procedures written by the firm for installation, setup, alignment and testing of the LIP and its installation. These procedures shall be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, any other applicable variance, and any emergency shutdown requirements. The procedures shall also provide for control of access to high laser radiation areas during installation using the procedures described in the ANSI Z136.1:2007 Standard For The Safe Use of Lasers (available from the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, Florida 32826) and, where applicable, state or local requirements.

12. A copy of the installation procedures specific to each model of the firm's LIPs shall be submitted with or as a supplement to the laser product report for that model prior to any introduction into commerce.

13. Records of the results of the installation tests which include the identification of the installer and operator shall be maintained by the variance holder.

14. The LIP shall be installed in accordance with any applicable state or local regulations pertaining to operation of Class IIIb or IV or Risk Group 3 laser systems for public use. It is the joint responsibility of the firm and the installation owner or manager to determine whether there are applicable state or local statutes and/or regulatory requirements and if so to meet those requirements prior to beginning to operate the LIP.

Unless otherwise specified by regulation (e.g., variance applications), all correspondence to be provided to CDRH shall be addressed to:

Center for Devices and Radiological Health
Magnetic Resonance and Electronic Products Branch
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue
WO66-G609
Silver Spring, MD 20993-0002

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