



Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MAY 19 2004

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FDA Docket No. 95V-0043/VAR 2

Mr. Bruce Floyd
Director, Regulatory Affairs/Quality Assurance
NexRay, Inc.
120 Albright Way
Los Gatos, California 95032

Dear Mr. Floyd:

The Center for Devices and Radiological Health (CDRH) is approving, in accordance with 21 CFR 1010.4(c)(1), the petition that NexRay, Inc. filed on March 23, 2004, for Variance 95V-0043/VAR 2. The items of the variance are:

A. Variance Number

95V-0043/VAR 2

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, unless renewed, shall terminate five years from the date of this letter.

D. Product for which Variance is Granted

This variance is applicable to the "VASCO" Scanning Beam Digital X-Ray System manufactured by NexRay, Inc. (formerly Cardiac Mariner, Inc.). The VASCO system is a stationary, C-arm based, low-dose, real-time digital x-ray system intended for real-time fluoroscopic applications where medically indicated. The intended use of this device is general purpose fluoroscopic imaging, using a different geometry than is used with a conventional fluoroscope. This variance is for the VASCO system as specifically described in the variance application. Any change in the dimensions, configuration, intended use or operating parameters will require the submission of a new variance request for the changes.

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E. Provisions from which Variance is Granted

Variance is granted from a provision of 21 CFR 1020.32(g) requiring that fluoroscopic x-ray systems be provided with a means to limit the source-skin distance (SSD) to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile fluoroscopes. In addition, for image-intensified fluoroscopes intended for special surgical applications that would be prohibited at the source-skin distances specified in this paragraph, provision may be made for operation at shorter source-skin distances, but in no case less than 20 centimeters. All other provisions of the performance standard for fluoroscopic equipment remain applicable to the VASCO system..

F. Conditions under which the Variance is granted

In lieu of the requirements referred to in section E, above, the following conditions shall apply to the fluoroscopic equipment manufactured under this variance:

1. A means shall be provided to limit the source-skin distance to not less than 2.5 centimeters.
2. The information provided to users pursuant to 21 CFR 1020.30(h) shall contain, as part of the adequate instructions concerning fluoroscopic safety, procedures and precautions that may be necessary because of unique features of the equipment, including recommended technique factors for a representative sample of fluoroscopic examinations for which the systems are designed, including data on tabletop or skin exposure resulting from these technique factors.
3. A section 510(k) premarket notification submission is cleared by the Office of Device Evaluation for this device before introduction into commerce.
4. An Initial Report is submitted to the Office of Compliance which provides the test and quality control programs to certify to all other applicable performance standards for diagnostic x-ray equipment.

G. Basis for Approval of Variance

In accordance with 21 CFR 1010.4(a), the CDRH has determined that the requirement of the fluoroscopic equipment standard referred to in Item E are not appropriate to the VASCO system. Suitable means for radiation safety and protection will be provided by constraints on the design.

H. Certification Label

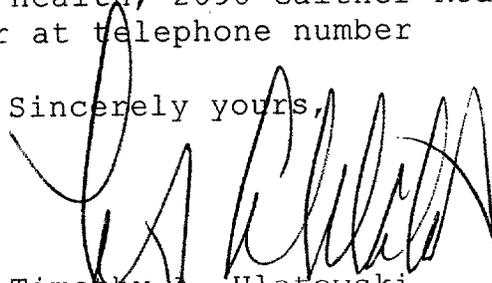
The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

"This product is in conformity with performance standards for diagnostic x-ray systems and their major components under 21 CFR Part 1020, except with respect to those characteristics authorized by Variance Number 95V-0043/VAR 2."

Except for the confidential material, this variance action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration. The variance will apply to products manufactured on or after the effective date, and will remain in effect until the termination date, unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

If you have any questions concerning this variance, you may contact Mr. Tom L. Mosely, Diagnostic Devices Branch (HFZ-322), Division of Enforcement B, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850, or at telephone number (301) 594-4639.

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health