DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JAN 18 2001

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Ted L. Parrot
Vice President Quality Assurance
Regulatory Affairs
GE OEC Medical Systems Inc.,
General Electric Company
384 Wright Brothers Drive
Salt Lake City, Utah 84116-2862

FDA Docket No. 00P-1577/CP1

Dear Mr. Parrot:

The Center for Devices and Radiological Health (CDRH) is approving, in accordance with 21 CFR 1010.4(c)(1), the petition filed by GE OEC Medical Systems., dated October 18, 2000, for a Variance on the Miniview mobile C-arm. The items of the variance are:

A. Variance Number

00P-1577/CP1

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 on this letter, or the effective date of any new regulations concerning small format c-arm x-ray systems, whichever comes first.

D. Products for Which Variance is Granted

This variance is applicable to the Miniview mobile C-Arm manufactured by GE OEC Medical Systems. This product as described by the manufacturer is a small format, low intensity system for real time fluoroscopic imaging in a miniature c-arm configuration. This device is intended to be used for the examination of extremities only. This variance is granted only for the specific unit as described in your application. Any change in the dimensions, intended use, available technique factors entrance exposure rate (presently limited to 9 R/min) or other parameters will require the submission of a new variance request.

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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 the product shall 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 product.

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 20 centimeters (or 10 centimeters with the spacer removed for surgical procedures as determined by the physician).

2. As part of the adequate instructions concerning fluoroscopic safety procedures and precautions that may be necessary because of unique features of the equipment, the information provided to users pursuant to 21 CFR 1020.30(h) shall contain the following: (a) a warning concerning the potential for, and hazards of, increased patient exposure associated with fluoroscopic techniques employing short source-skin distances; (b) recommended technique factors for a representative sample of fluoroscopic examinations for which the system is designed, including data on tabletop or skin exposure resulting from these technique factors.

3. Each GE OEC Miniview Mobile C-arm shall be clearly labeled as follows: "This device is intended for the examination of extremities only. It is not to be used for pediatric/infant whole body imaging".

G. Basis for Approval of Variance

In accordance with 21 CFR 1010.4(a), the CDRH has determined that the requirements of the fluoroscopic equipment standard referred to in section E are not appropriate to the GE OEC

Miniview Mobile C-Arm. Suitable means for radiation safety and protection will be provided by constraints on the design and by supplemental information and labeling provided to users.

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 00P-1577."

Except for the confidential material, this variance action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration (FDA). 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, or new regulations become effective concerning these types of products.

If you have any questions concerning this variance, you may contact Mr. William C. Maloney, Diagnostic Devices Branch (HFZ-322), Division of Enforcement I, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850, or at (301) 594-4591.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health