

September 1, 1999

Mr. Tom L. Mosely
Diagnostic Devices Branch (HFZ-322)
Division of Enforcement I
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

4631 '00 MAR 17 AIO:32

Reference: Request for Extension of Variance No. 84V-0380
Current Termination Date: April 12, 2000

Dear Mr. Mosely:

We hereby request a five year extension of our current variance from the requirements of 1020.32(h)(2) of the Performance Standard for Radiographic Equipment (21 CFR 1020.31) and the requirements of 1020.32(f) of the Performance Standard for Fluoroscopic Equipment (21 CFR 1020.32).

The current variance bears Accession No. 85A-0169-03. All of the conditions of that variance remain the same.

Sincerely,

FLUOROSCAN IMAGING SYSTEMS



William J. Engel
Quality Assurance/Regulatory Affairs Manager

WJE/jh

84V-0380

EXP2

December 13, 1999

Mr. William Maloney
Diagnostic Devices Branch (HFZ-322)
Division of Enforcement I
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

Reference: Request for Extension of Variance No. 84V-0380
Current Termination Date: April 12, 2000

Dear Mr. Maloney:

As per our telephone conversation last Friday afternoon, I am amending the request for a variance extension dated September 1, 1999. I apologize for any inconvenience this may have caused.

We hereby request a five-year extension of our current variance from the requirements of 1020.32(f) of the Performance Standards for Fluoroscopic Equipment. The current variance bears Accession No. 85A-0169-03.

All of the conditions of the variance remain the same, with the exception of the following:

The optional radiographic spot film device to our Fluoroscopic Imaging System, reported in our Initial Report (Accession No. 8511719) is no longer offered. For your convenience, I have included a copy of the current variance with all references to "radiographic equipment" highlighted, as they may be deleted.

If you have any further questions or require any additional information please feel free to call me.

Sincerely,

FLUOROSCAN IMAGING SYSTEMS



William J. Engel
Quality Assurance/Regulatory Affairs Manager

WJE/jh

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 9 1995

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FDA Docket No. 84V-0380
Accession No. 85A-0169-03

Mr. Larry M. Frase
Quality Control/Service Manager
FluoroScan Imaging Systems, Inc.
650 Anthony Trail
Northbrook, Illinois 60062

Dear Mr. Frase:

It has been brought to my attention that the specific conditions under which this variance was granted may not be appropriate to the device for which the variance was granted. A thorough review of those conditions has resulted in a slight modification of Section F, "Conditions Under Which the Variance is Granted," to more correctly define conditions applicable to your device.

The Center for Devices and Radiological Health (CDRH) is amending Variance 84V-0380, as amended on October 31, 1991, and as extended, in accordance with 21 CFR 1010.4(c)(1), with an effective date of April 14, 1995, upon petition for such extension by Fluoroscans Imaging Systems, Inc., filed on January 13, 1995. The items of the amended variance are:

A. Variance Number

84V-0380

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 on April 12, 2000.

D. Product for Which Variance is Granted

This variance is applicable to the FluoroScan Imaging System manufactured by FluoroScan Imaging Systems, Inc., (Formerly HealthMate, Inc.). The product is a small-format, low-intensity system for real-time fluoroscopic and radiographic x-ray imaging in a miniature c-arm

configuration. The device is intended to be used for examination of extremities only.

E. Provisions From Which Variance is Granted

Variance is granted from a provision of 21 CFR 1020.32(f) 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.

In addition, variance is granted from a provision of 21 CFR 1020.31(i)(2) requiring that the product be provided with means to limit the source-skin distance to not less than 30 centimeters on mobile or portable radiographic systems other than dental. All other provisions of the performance standard for radiographic 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 and radiographic equipment manufactured under this variance:

1. A means shall be provided to limit the source-skin distance to not less than 9 centimeters.
2. As part of the adequate instructions concerning fluoroscopic and radiographic 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 the hazards of, increased patient exposure associated with fluoroscopic or radiographic techniques employing short source-skin distances; (b) a discussion of recommended procedures for minimizing patient exposure, including information on recommended imaging systems or film/screen combinations; (c) recommended technique factors for a representative sample of fluoroscopic and radiographic examinations for which

the systems are designed, including data on tabletop or skin exposure resulting from these technique factors.

3. Each FluoroScan imaging system shall be clearly labeled as follows: "For Examination of Extremities Only."

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 and the requirement of the radiographic equipment standard referred to in section E are not appropriate to the FluoroScan Imaging System. Suitable means for radiation safety and protection will be provided by constraints on the design and by supplemental information and labeling provided to users.

A variance for a similar product was granted under Docket Number 76P-0418, effective February 16, 1977. A more detailed discussion of the basis for approval of the variance is in the FEDERAL REGISTER notice (42 FR 11050) regarding the granting of such a variance.

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 84V-0380."

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.

Because your product is a medical device, certain other regulations under the 1990 Safe Medical Devices Act and the Federal Food, Drug, and Cosmetic Act are applicable to your product. For further information concerning compliance with these regulations, you may contact Mr. Tom L. Mosely, Diagnostic Devices Branch (HFZ-322), Division of Enforcement I, Office of Compliance, Center for Devices and Radiological

Page 4 - Mr. Larry M. Frase

Health, 2098 Gaither Road, Rockville, Maryland 20850, or at
telephone number (301) 594-4591.

Sincerely yours,

for *Adrianne Gold*
Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health