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**GE Medical Systems**  
*OEC*

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Salt Lake City, UT 84116  
801-328-4300

April 14, 2000

Documents Management Branch (HFA-305)  
Food and Drug Administration  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

Re: Variance Application

Attention: Documents Manager

In accordance with 21 CFR 1010.4, OEC Medical Systems hereby submits application for a variance from the source-skin distance requirement of the performance standard for fluoroscopic equipment [21 CFR1020.32(g)], as it applies to the *Mini 6800 Mobile C-arm*.

The following information is provided in support of this application:

1. The Mini 6800 Mobile C-arm (hereafter called 6800 C-arm), manufactured by OEC Medical Systems, is a small C-arm configuration, image-intensified fluoroscopic system. The 6800 C-arm is intended to provide the physician with fluoroscopic visualization of the patient during surgical orthopedic procedures and extremity examinations.

A summary of relevant 6800 C-arm specifications is provided as follows:

DOV-1264

VAR1

<b>Monoblock X-ray Tube/ Generator</b>	
High Voltage Range	40 to 80 kVp
Tube Current Range	20 to 160 $\mu$ A (0.020 to 0.160 mA)
Automatic Dose Rate Control	Normal and Low Dose settings
Entrance Exposure Rate (max.)	2.3 R/minute @ 20 cm SSD (with spacer) 9.0 R/minute @ 10 cm SSD (minimum)
Focal Spot	0.050 mm
Collimator	Circular two-position for selected field of view
Image Intensifier	Dual mode, 4/6-inch field of view
Source-Image Distance	48 cm (fixed)

2. Like the other commercially available mini C-arms (FluoroScan, Lunar, and OEC 6600), the 6800 C-arm offers a compact and economical imaging system that is well suited for orthopedic surgery and diagnostic examination of both the upper and lower extremities.

These surgical applications require that the open area between the x-ray head and the image intensifier be large enough to allow the physician to manipulate surgical tools (30-38 cm). This is not possible if the minimum source-skin distance (SSD) is limited to that required by the performance standard, i.e. 30 centimeters for mobile fluoroscopes or 20 centimeters for fluoroscopes intended for specific applications.

3. The 6800 C-arm deviates from the performance standard by providing a minimum SSD less than 20 centimeters as required for fluoroscopes intended for specific applications.

OEC proposes that the 6800 C-arm provide SSD not less than:

- 20 centimeters with the removable spacer attached to the x-ray head,
- 10 centimeters with the spacer removed for surgical procedures as determined by the physician.

4. A reduction in the minimum SSD allows the 6800 C-arm to utilize a relatively short source-image distance (SID) of 48 centimeters. Consequently, the x-ray technique factors necessary to produce high quality diagnostic images are proportionately lower than those employed by a conventional fluoroscope (with 100 centimeter SID). For example, the x-ray tube current range of the 6800 C-arm is 0.020 to 0.160 mA (20-160  $\mu$ A) compared to 0.2 to 5.0 mA, typical of a conventional mobile C-arm. This results in comparable entrance dose rates when the patient anatomy is positioned as close as possible to the image intensifier. The table below shows the 6800 C-arm dose rates are actually lower for the same extremity examination when compared to either the OEC Series 9800 conventional C-arm or the OEC Mini 6600 C-arm (also see Attachment A).

### Six-inch Field Dose Rates (mR/min)

Extremity	Thickness (cm)	Series 9800	Mini 6600	Mini 6800
Hand	3.40	137	53	43
Wrist	4.45	140	61	38
Forearm	5.38	172	56	52
Foot (lateral)	6.91	212	100	71
Foot (AP)	7.95	219	105	84
Ankle	7.29	264	108	83
Knee (lateral)	10.24	380	218	163
Knee (AP)	10.33	373	189	150
Shoulder	13.20	818	820	492

The SID of mini C-arms that are currently commercially available is 40 to 45 centimeters. The SID of the 6800 C-arm is increased to 48 centimeters in response to physicians' requests for additional surgical tool working space between the x-ray head and the patient. The resulting working space is 38 centimeters when the skin spacer is removed for surgical procedures as determined by the physician. The working space is reduced to 28 centimeters with the skin spacer attached to the x-ray head for routine extremity examinations.

5. Suitable means of radiation protection is provided by constraints on the design and supplemental information provided to users.

The minimum SSD of 10 centimeters is established by the collimator enclosure that is permanently attached to the x-ray tube housing. The SSD increases to 20 centimeters with the skin spacer attached to the x-ray head. Prototype testing shows maximum dose rates to be around 9 R/minute at the 10 centimeter minimum SSD<sup>1</sup> (see Attachment B).

The user manuals contain supplemental information and precautions that may be necessary because of the shortened SSD.

The product labeling specifies that the 6800 C-arm is intended for extremity examinations and is not suitable for pediatric/infant whole-body imaging (see Attachment C).

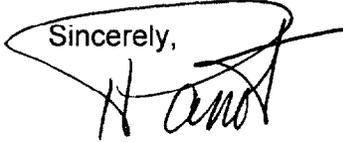
6. OEC requests the variance be in effect for a period of time not less than five years from the date of issue.

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<sup>1</sup> This corresponds to entrance exposure rate of 3 R/minute at 30 centimeters distance from the image intensifier as measured in accordance with 21 CFR 1020.32(e)(2).

If you require additional information to evaluate and act upon this application, please contact me at 801-536-4694.

Sincerely,

A handwritten signature in black ink, appearing to read "Ted L. Parrot", enclosed within a hand-drawn oval.

Ted L. Parrot,  
Vice President, Quality Assurance/Regulatory Affairs  
and Official Correspondent

Enclosures:

Attachment A – Fluoroscopic Technique and Dose Rate for Extremity Examinations

Attachment B – Mini 6800 Maximum Entrance Dose Rate

Attachment C – Product Labeling

TLP/jw