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Department of Health and Human Services
Center for Devices and Radiological Health
Office of Device Evaluation
Premarket Notification section

Smit Roentgen Approbation
XB36150/96-09-26/RR/LS

XB 36150/RR/LS. 1996.09.26

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

for

SMIT ROENTGEN FIBRE INTERSPACED X-RAY GRIDS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990

The undersigned certifies that the 510(k) Premarket Notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence

The information is summarized as follows:

1. The Fibre Interspaced X-ray grids are subject to Federal Performance Standards, defined in 21CFR- 982.1910

2. The Fibre Interspaced X-ray grids will be manufactured in accordance with voluntary safety standards, such as IEC publication 627

3. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when properly used.

Ing. R.W. Rijntjes
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