PHILIPS

Philips Medical Systems

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DEC 23 1996

Department of Health and Human Services
Center for Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section.

QA Department XRD Best
XBQ87-960792/HD/wp

1996.05.20

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

for the optional package:

SPINE

for use in PHILIPS EasyVision X-Ray workstations

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.
The undersigned certifies that the 510(k) Pre-Market notification for the above referenced products contains adequate information and data to enable CDRH to determine substantial equivalence.

This information and data is summarized as follows:

1. The information for Users contains comprehensive information to insure safe and effective use;

2. Past experience with substantially equivalent predicate devices/methods has shown our device to be safe and effective when used as directed in the Information for Users.

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