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PHILIPS

**Philips Medical Systems**

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

Quality Assurance Dpt. XSB/XCB  
XB030-950608/RR/wp

1995.05.30

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

**for the optional package:**

**CT/MR MATCHING**

**for use in PHILIPS EasyVision CT/MR 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 has shown our device to be safe and effective when used as directed in the Information for Users.

  
R. W. Rijntjes  
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