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Philips Medical Systems MAY 14 1997

P.O. Box 10000, 5680 DA Best, The Netherlands

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

TQM XRD Best
XDB087-970107/RR/rr

1997.02.25

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

for

PHILIPS INTEGRIS H 5000 and BH 5000 CARDIO / VASCULAR SYSTEMS

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 product contains adequate information and data to enable CDRH to determine substantial equivalence.

This information and data is summarized as follows:

1. The Integris H 5000 / BH 5000 systems are subject to Federal Performance Standards, defined in 21CFR - part 1000;

2. The Integris H5000 / BH 5000 systems will be manufactured in accordance with voluntary safety standards, such as UL 187 and UL 2601;

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

4. 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.

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