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K970640

510(k) Summary of Safety and Effectiness

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems North America Company herewith submits a Summary of Safety and Effectiveness.

CLASSIFICATION NAME: Table 21CFR 892.1980 (90 IXR)
Spot Film Device 21CFR 892.1670 (90 IXL)
Class II

COMMON/USUAL NAME: R/F System (R/F Table)

TRADE/PROPRIETARY NAME: PHILIPS EasyDIAGNOST

ESTABLISHMENT No. 1217116

PERFORMANCE STANDARDS:

This device complies with the federal X-Ray performance standards (CFR 1020.30, .31, .32) as well as with the relevant national and international standards for Electrical and Mechanical Safety (UL 187, IEC 601-1, IEC 601-2-7).

SYSTEM DESCRIPTION:

The Philips EasyDIAGNOST is a multi-functional R/F system consisting of a floor-mounted tilting patient support table and a spotfilm device holding an image intensifier and the TV camera. The tabletop can be moved by motor in longitudinal and lateral directions. The spot film device tilts with the table, and can be moved in three directions, relative to the table and to the patient. As a fully integrated system, it can be configured with generators from the Philips Medio, Super CP, and OPTIMUS families, with digital spot film cameras from the Philips DSI family, and with a Philips EASYVISION workstation. The system comes with a trimode Image Intensifier, XTV imaging system, Philips glass or metal X-ray tube(s), and TV monitor(s). An optional dedicated ultrasound system (Scanner 200X) can also be added.

The system can also be extended with an overtable tube which operates on a bucky tray inside the table and/or on a bucky wallstand (so-called second plane). This second plane option is identical to a Philips bucky DIAGNOST system, except for the table itself.

Philips Grid Controlled Fluoroscopy (GCF) can be provided using an SRM (metal) grid-switched X-ray tube. GCF improves overall image quality and provides dose reduction through precise control of fluoroscopic pulse shapes, eliminating excess radiation associated with pulse ramping and trailing effects of conventional pulsed fluoroscopy.

EQUIVALENCE INFORMATION:

The Philips EasyDIAGNOST is a modification of, and substantially equivalent to, the Philips DIAGNOST 76 plus manufactured by Philips Medical Systems. The DIAGNOST 76 plus received 510(k) clearance November 24, 1992 (see 510(k) K924593). The DIAGNOST 76 plus was found substantially equivalent to the DIAGNOST 73, which is a pre-amendment device. The intended use of the Philips EasyDIAGNOST is the same as for the Philips DIAGNOST 76 plus. Both systems make use of equivalent technology.

SAFETY INFORMATION:

Throughtout the world, R/F systems are indispensable in daily practice for routine X-ray diagnosis. Industry and users have many years of experience with this type of equipment. The Philips EasyDIAGNOST uses mature technology and is designed to be in compliance with National and International safety standards.

The software used in the EasyDIAGNOST is equivalent to the software used in the predicate device.

The results of the hazard analysis, combined with the appropriate preventive measures taken indicate the device is of minor level of concern, as per the August 29, 1991 issue of the "Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review".

Philips Medical Systems North America Company feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence.