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## 510(k) Summary

K964990

### Hitachi SX-VA30

Common/Classification Name: Angiographic X-ray  
System, 21 CFR 892.1600

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#### A. LEGALLY MARKETED PREDICATE DEVICES

The **Hitachi SX-VA30 C-Arm Angiographic/Fluoroscopic System** is substantially equivalent to the presently marketed **Hitachi SF-VA100** as distributed by **Hitachi Medical Systems America** (as cleared in K945400) and the **Philips Medical Systems Integris V3000** (K923813). The SX-VA30 is manufactured by **Hitachi Medical Corporation**, Hitachi Hagoromo Building, 1-2-10 Uchi-Kanda, Chiyoda-Ku, Tokyo, 101, Japan. This 510(k) is submitted because the SX-VA30 is a new device.

#### B. DEVICE DESCRIPTION

The **Hitachi SX-VA30 C-Arm Angiographic/Fluoroscopic System** is a single plane, ceiling suspended C-Arm system intended for angiographic and related diagnostic and therapeutic procedures requiring fluoroscopic and radiographic imaging. It is configured with other components such as high voltage generator, x-ray tube assembly, DSA system, etc., to form a complete fluoroscopy and angiography system. The C-arm is disposed on the isocenter and is movable in a wide range to permit studies of the patient's whole body from the head to the foot from a number of angles.

The SX-VA30 system consists of the SX-VA30 Ceiling-traveling C-Arm Support with ceiling track rails, the control electronics box, the display panel, and the table-side control panel. The SX-VA30 is also configured with the DFA-100-30 digital subtraction angiography system, and several other components which have been previously cleared by FDA as a part of K945400.

While the system is configured with a digital imaging system as

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standard, conventional film radiography may be employed as an option.

In the digital domain, acquired images may be stored in a variety of formats. During acquisition cycles, the progress of the study can be monitored as it occurs, largely eliminating the need for studies to be redone.

#### **C. INTENDED USE**

The **Hitachi SX-VA30 C-Arm Fluoroscopic/Angiographic System** is intended to visualize anatomical structures by converting a pattern of x-radiation into an image through electronic amplification and recording, and, when used with injection of contrast medium, to visualize the heart or blood vessels.

#### **D. SUBSTANTIAL EQUIVALENCE SUMMARY**

The **Hitachi SX-VA30** has the *same* intended use and target population as the predicate devices, and has *equivalent effectiveness* for its intended use.

#### **E. TECHNOLOGICAL CHARACTERISTICS**

The technological characteristics of the **Hitachi SX-VA30** are the same as for the **Philips Integris V3000 C-Arm** system, and except for the support system, are the same as for the **SF-VA100**.

Subsystem components such as X-ray generators, X-ray tubes, X-ray columnators and receptors, and digital processing systems are identical or very similar to the corresponding components of the **SF-VA100**.

Most of the differences between the predicate devices and the **SX-VA30** are in areas of incremental improvements and have been gained using technology common to both designs.

#### **F. TESTING**

The **SX-VA30** was tested in the same manner as was the previously cleared **SF-VA100**. This testing addressed the following issues:

- (1) Electrical Safety;
- (2) Conformance to the General Rules for Medical X-Ray Equipment, JIS Z 4701-1988 (Japanese Industrial Standard); and
- (3) Conformance to the applicable provisions of the FDA Performance

Standards for Ionizing Radiation Emitting Products (21 CFR 1020), particularly the section for Fluoroscopic Equipment (21 CFR 1020.32).

**G. CONCLUSIONS**

**Hitachi Medical Systems America** has demonstrated that the **Hitachi SX-VA30** is substantially equivalent to the Hitachi SF-VA100 and the Philips Integris V3000.