

510 (k) SUMMARY

I. GENERAL INFORMATION:

Establishment:

- Address: Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ. 08830

- Registration Number: 2240869

- Contact Person: Kathleen Rutherford
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Date of Summary Preparation:

Device Name:

- Trade Name: Fluorospot T.O.P.

- Common Name: Digital Imaging System

- Classification Name: Image Intensified Fluoroscopic
X-ray System

- Classification: Class II

Performance Standards: 21 CFR, Subchapter J

All system components to which the above standard applies are certified to conform with 21 CFR subchapter J

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION.

Device Description:

The Siemens Fluorospot T.O.P. is a digital imaging system for radiographic/fluoroscopic, angiographic and interventional procedures. The Fluorospot T.O.P. is designed to acquire, record and display radiographic images. The Fluorospot T.O.P. digital imaging system, is an optional integral component of a radiographic/fluoroscopic universal interventional angiographic suite, as such it is not considered a stand alone device.

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Intended Use:

The Fluorospot T.O.P. is intended for use with radiographic/fluoroscopic and universal interventional angiography x-ray systems to digitally acquire, record and display radiographic images. The Fluorospot T.O.P. enables the trained healthcare professional to consistently acquire high quality images for fluoroscopic examinations with contrast medium, digital tomographical exposures. urological examinations, vascular and non-vascular procedures as well as general angiography, interventional angiography, peripheral angiography and DSA (Digital Subtraction Angiography).

Technological Characteristics:

The Fluorospot T.O.P. is a 10 bit digital imaging system. Images can be acquired and displayed in two formats, 1024^2 and 2048^2 . Radiographic/Fluoroscopic x-ray systems configured with the Fluorospot T.O.P. with 2048^2 format and large image fields will acquire and display images with detailed recognition and resolution. The Fluorospot T.O.P. is designed to directly interface with the Siemens Sienet (Siemens Picture Archival Communication System) and transfer data in a DICOM 3.0 and ACR/NEMA formats.

General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the X-ray studies to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

Substantial Equivalence:

The Fluorospot T.O.P. digital imaging system has similar technological characteristics and intended use as the predicate devices described in the Equivalency Information section of this premarket notification. Siemens Medical Systems, Inc. believes that the Fluorospot T.O.P. , the subject of this premarket notification, is substantially equivalent to the following medical devices currently in commercial distribution.

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Model	Company	FDA K-Number
Fluorospot T.O.P.	Siemens Medical Systems, Inc.	K914525
Polytron T.O.P.	Siemens Medical Systems, Inc.	K933664
QL MultiPulse 2048	InfiMed, Inc.	K933299



Kathleen Rutherford
Manager, Regulatory Submissions

5/14/96
Date