

MAY 14 1997

## 510(k) Summary

### Multix TOP/ PRO Radiographic X-ray Table

Submitted by:

Siemens Medical Systems, Inc.  
186 Wood Avenue South  
Iselin, NJ 08830  
Establishment Registration Number:  
2240869

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

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2. **Device Name and Classification:**

Trade Name: Multix TOP/PRO Radiographic X-ray Table  
Classification Name: Radiologic Table  
Classification Panel: Radiology  
CFR Section: 21 CFR §892.1980  
Device Class: Class II  
Device Code: 90IZZ

3. **Intended Use:**

The Multix TOP/ PRO Radiographic X-ray Table is a patient table used in conjunction with the Siemens Multix PRO - and TOP Systems radiographic devices. The table allows for radiographic exposures of the entire body, specifically the skull, spinal column, chest and abdomen, as well as the extremities. Applications can be performed with sitting, standing or prone patient positioning.

4. **Substantial Equivalence:**

The Multix TOP/ PRO Radiographic X-ray Table is substantially equivalent to the following devices in commercial distribution:

# SIEMENS

- Multix U/C, K803130  
Siemens Medical Systems, Inc.
- Compax 40E\*, K884930  
General Electric Co.

\* Please note, it is believed the GE Compax 40E is described in the FDA Clearance for the GE Compax 40 under 510(k) K884930.

5. **Device Description:**

The Multix TOP/ PRO Radiographic X-ray Table is a floor mounted patient table that is free-floating and constructed of carbon fiber material. The patient table is offered in two configurations and is a slightly modified, upgraded version of the original Multix U/C. One configuration is the motorized, adjustable height patient table which is used in the Multix TOP and PRO Systems. The other configuration (PRO FIX) is the fixed height patient table which is used in the Multix PRO Systems.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**

The Multix TOP/ PRO Radiographic X-ray Table has the same technological characteristics as the predicate Siemens Multix U/C Table and GE Compax 40E Table. The table is not a stand alone device but is an integral part of an overall radiographic system. All systems contain the same basic configurations with the following standard components: X-ray table, cassette holders, tube supports, X-ray tubes, collimator, Bucky wall stand and X-ray generator.

  
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