

DEC 18 1996

Summary of Safety & Effectiveness

Product Identification:

Name: Mobile CT ProSpeed

Manufacturer: GE - Yokogawa Medical Systems
7-127 Asahigaoka, Hino-shi
4-chome, Tokyo 191, Japan

Distributor: GE Medical Systems
3000 N. Grandview
Waukesha, WI 53188

K963896

Mobile Coach: Calumet Coach Co.
2150 Dolton Ave.
Calumet City, IL 60409

Indications for Use:

The Mobile CT ProSpeed is indicated for head and whole body x-ray computed tomography applications to be mounted in a trailer. The Mobile CT ProSpeed has the same indications for use as the CT ProSpeed Plus (formerly known as CT Sytec 8000 K913485) and CT ProSpeed Family with HiLight Detector K944013.

Device Description:

The device is an x-ray computed tomography scanner consisting of a gantry, patient table, console, computer, and associated accessories, mounted within a trailer.

Materials: Materials and construction are equivalent to the CT ProSpeed Plus and are CT ProSpeed Family with HiLight Detector which are compliant with UL 187, IEC 601-1, and 21 CFR Subchapter J.

Design: The design is essentially the same as the CT ProSpeed with larger mounting bolts for the table and gantry as well as special instructions for the set-up and take down of the system.

Energy Source and Exposure Levels: The energy source is the same as the CT ProSpeed Plus and CT ProSpeed Family with HiLight Detector with the same x-ray tube and generator.

Principals of Operation: The same as the CT ProSpeed Plus and CT ProSpeed Family with HiLight Detector.

Features: The same as the CT ProSpeed Plus and CT ProSpeed Family with HiLight Detector.

Accessories: The same accessories as the CT ProSpeed Plus and CT ProSpeed Family with HiLight Detector.

Marketing History:

The CT Mobile ProSpeed is substantially equivalent to the currently marketed CT ProSpeed Plus, (K913485) and CT ProSpeed Family with HiLight Detector (K944013).

Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are controlled by compliance with industry standards (UL 187 & IEC 601-1), the Federal performance standard (21CFR Subchapter J), and warnings in the labeling.

Conclusions:

The CT Mobile ProSpeed is intended to provide a CT scanner capable of being transported between or shared with other medical facilities to help reduce health care costs and provide CT services to areas where they might not otherwise have them. It is substantially equivalent to the CT ProSpeed Plus and in design, CT ProSpeed Family with HiLight Detector construction, energy source, exposure level, principle of operation, features, and accessories.