

JAN 17 1997

K964583

Summary of Safety and Effectiveness

1. Device Name

XRT-7.0 option for CT scanners.

2. Submitter

Elscont Inc.,
505 Main Str.
Hackensack, NJ 07601.

3. New Features Description

XRT-7.0 option was added to CT Twin flash. The option adds an X-ray tube with 7.0 MHU anode heat capacity to the options list.

4. Predicate Device

CT-Twin *flash* submitted in "HRSW Option for CT-Twin Flash", K945512.

5. Safety

The safety of the device is equivalent to the safety of the predicate device, CT Twin *flash*.

The 7.0 MHU tube option is mechanically and electrically very similar to the previous X-ray tubes and the software driver is the same.

6. Effectiveness

The effectiveness of the device was not significantly changed in respect to the predicate device, CT Twin *flash*: The increased heat capacity is more convenient to use due to shorter delays for tube cooling.

7. Substantial Equivalency Statement

Based on the above considerations, it is Elscint's opinion that CT scanners with the added XRT-7.0 option is substantially equivalent in safety and effectiveness to its predicate device, CT-Twin flash submitted in "HRSW Option for CT-Twin Flash", K945512.