

Summary of Safety and Effectiveness

JUL - 3 1996

1. Device Name

SeleCT/SP

2. Submitter

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

3. Description of Main Features

The SeleCT/SP is a cost effective spiral scanner, with compact siting requirements and real-time image processing functions.

4. Predicate Devices

- HeliCAT, K930090.
- Other related devices:
 - ◊ Exel 905 GT, K884667
 - ◊ AngioCT, K932508/B
 - ◊ ProVision by Algotec Ltd., Raanana, Israel, K954678

5. Safety

The SeleCT/SP complies with IEC601-1 safety standard. Its safety is not significantly different from the predicate device, HeliCAT.

Its scan modes and radiation doses are similar those of the predicate device.

The laser localizer system is Class I and does not therefore significantly change the safety of the device.

6. Effectiveness

The effectiveness of SeleCT/SP is not significantly changed in respect to the predicate device, HeliCAT: the longer scan time and smaller gantry aperture affect the convenience of use; the lower spatial resolution and X-ray power are similar to those of Exel 905 GT.

7. Substantial Equivalency Statement

Based on the above considerations, it is Elscint's opinion that the SeleCT/SP CT scanner is substantially equivalent in safety and effectiveness to the predicate device, HeliCAT, K930090.