

Device Description Summary:

The VCAR option to the VISION FX-80 Gamma Camera and Power Station (FX-80&PS/VCAR) is an accessory upgrade to the previously cleared FX-80 Gamma Camera (K935273) and Power Station (K912753). This accessory enables the system to perform electronic collimation for positron emission tomography (PET) of radioisotopes within the human body. The FX-80&PS/VCAR utilizes proprietary coincidence detection electronics and software to perform electronic collimation of gamma rays emitted from decay of radioisotopes in a patient. This process is called "Coincident Photon Emission Computed Tomography" (CPECT).

The FX-80&PS/VCAR allows the operator to acquire coincidence imaging data by controlling the detector electronics and processors in coincidence imaging mode. The FX-80&PS/VCAR also includes the control, processing, and display screens to perform reconstruction of 2-D and 3-D information from the acquired datasets.

Intended Use:

The VCAR option to the VISION FX-80 Gamma Camera and Power Station produces images which depict the anatomical distribution of radioisotopes within the human body, for interpretation by medical clinicians. The system is intended for whole body nuclear imaging.

Technological Characteristics:

The FX-80&PS/VCAR has been designed to perform imaging of PET isotopes in a way which is very similar to traditional PET systems (e.g., the GE Quest 300) and gamma camera PET systems (e.g., ADAC's MCD option to the VERTEX Epic System). The FX-80&PS/VCAR is very similar to both predicate devices.

Each system detects radioisotope emissions from the human body and integrates the acquired emission data over time to produce an image representing a quantification of emissions from the imaged region. All three units utilize the same theory of operation.

In all three systems, detection events from opposing detectors are compared, to determine if both detected an event almost simultaneously. Coincident events undergo

additional processing to generate images which show the frequency of annihilation events due to radioisotopes in the area being imaged.

Each of the three systems have additional post-acquisition processing systems which further manipulate the image data to perform 2-dimensional and 3 dimensional reconstructions of the imaged area.

In addition, all three systems are able to utilize any FDA-approved positron-emitting radioisotope (e.g., Fluorodeoxyglucose [FDG]) to generate images.

Summary of Testing:

Major performance parameters have been measured using industry-standard test methods to determine that the device meets its system performance specifications and performs in a fashion similar to predicate devices.

Conclusion:

The VCAR option for the VISION FX-80 Gamma Camera and Power Station was developed and validated in accordance with the Company's product and software development procedures. System testing and validation demonstrates that the system meets its published specifications, performs as well as or better than the currently marketed product, and is safe and effective for its intended use.
