

K964712

FEB 20 1997

PICKER INTERNATIONAL 510(k) NOTICE

PRISM XPVT SYSTEM

E: SUMMARY OF SAFETY AND EFFECTIVENESS

This is a summary of the information submitted by Picker International, Inc. to the Office of Device Evaluation (DRAERD) of the FDA as required by the Federal Food, Drug, and Cosmetic Act as amended on November 18, 1990 in section 807.92(c) for the Prism XPVT system.

The Prism XPVT system is a new gantry for a gamma camera system. This device is intended to be used for diagnostic imaging of organs and lesions. There is no change of intended use from that of the predicate device. This device includes adding hardware and software to a gamma camera system.

Functional specifications and operator's instructions (preliminary) are included in the attachments. Final documentation will be provided with production units.

The Prism XPVT system is substantially equivalent to legally marketed devices. The system will be operated by trained health care professionals who are responsible for Nuclear Medicine diagnostic examinations. The Prism XPVT system will be certified to electrical safety standards (IEC-601 or UL-544) by a third party organization prior to use on human patients. Labeling (Product Bulletin and Operator's Manual) will be provided to the user of the equipment.

Laboratory tests will be run to validate the image quality performance of the system. The product will perform in accordance with the development specifications. A matrix was enclosed comparing the Prism XPVT to a predicate device and therefore we concluded that it is substantially equivalent to that legally marketed predicate device.

Picker has reviewed all known information and performed an investigation as to the causes of safety and effectiveness concerning the Prism XPVT. In addition, all information contained in this 510(k) Notice is accurate and complete.