

K955484

PICKER INTERNATIONAL 510(k) NOTICE

MAR 29 1996

XENON OPTION TO THE PRISM 3000 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 Xenon Option.

The Xenon Option to the Prism 3000 system is a modification of a gamma camera system. This device is intended to be used for diagnostic brain imaging. There is no change of intended use from that of the predicate device. This device includes a gamma camera system, xenon delivery system, xenon probe, system interface, and the necessary software.

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

The Xenon option to the Prism 3000 system is substantially equivalent to legally marketed devices. The Xenon option will be operated by trained health care professionals who are responsible for Nuclear Medicine diagnostic examinations. The Xenon option will be certified to electrical safety standards (IEC-601) 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.

Clinical tests have shown that the Xenon option is effective in diagnosing brain anomalies. The product will perform in accordance with the development specifications. A matrix was enclosed comparing the Xenon option 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 Xenon option. In addition, all information contained in this 510(k) Notice is accurate and complete.