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PICKER INTERNATIONAL 510(k) NOTICE

STEP OPTION TO THE PRISM DUAL HEAD 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 513(f)(3) for the STEP for Prism Dual Head (system).

The STEP Option to the Prism Dual Head system is a modification of 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 STEP option to the Prism Dual Head system is substantially equivalent to legally marketed devices. The STEP option will be operated by trained health care professionals who are responsible for Nuclear Medicine diagnostic examinations. The STEP option 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 have shown that the STEP option has minimized the degrading effects of body attenuation when compared to a standard gamma camera without STEP correction. The product will perform in accordance with the development specifications. A matrix was enclosed comparing the STEP 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 STEP option. In addition, all information contained in this 510(k) Notice is accurate and complete.