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Picker 510(k) Notice

K962010

epi-Scope Option

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 epi-Scope Option.

The epi-Scope Option will be used in a Computed Tomography X-ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This device may include signal analysis and display equipment, patient equipment supports, components and accessories.

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

The epi-Scope Option is substantially equivalent to legally marketed device. The epi-Scope Option is under control of health care professionals who are trained and responsible for computed tomography examinations. The epi-Scope Option will be used in certified CT Systems that comply with Federal Diagnostic X-ray Performance Standards.

Picker adheres to FDA GMPs, 21 CFR 1020.30-31, voluntary standards for safety/effectiveness (UL 187) all of which mandate that components are tested to minimize hazards (electrical, mechanical, and radiation).

Effectiveness is established by Picker's evaluation throughout all phases of the epi-Scope Option development. The product will perform in accordance with the development specifications. The epi-Scope Option represents the current state-of-the-art technology, therefore, is equivalent to legally marketed Advantage 3D Navigator Option manufactured by General Electric in Document Control No. K954355.

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