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510(k) Summary

Submitted by: Javad Seyedzadeh, Director of Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
Tustin, CA 92681
Tel.: 714-730-5000

Contact: Mark Stauffer, Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
Tel.: 714-730-5000

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- **Device Name**

Scatter Correction Volume Software for Toshiba Gamma Cameras, Model **NSSC-020A**

Common name: Gamma Camera Processing Software

Classification name: Emission Computed Tomography System

- **Predicate Device**

Toshiba GCA-7200A (K931297/A)

- **Description of Device**

This product is an optional software program available for the Toshiba DI-series devices. It is intended to give a user the ability to acquire scatter data during acquisitions, then remove the unwanted scatter data from the processed image data. Based on the Triple Energy Window method of Compton - Scatter Correction, this program calculates the location and amount of scatter data in each pixel and subtracts it from the patient data.

- **Intended Uses**

This program can be utilized for all traditional and accepted gamma camera applications. It is expected that its benefits will be realized primarily when the system is being used to acquire tomographic studies. The intended use of the gamma camera system is unchanged by this program. Toshiba believes that users will find the T.E.W method to be beneficial when performing dual-nuclide acquisitions, by enhancing the system's ability to detect the energy peaks of each

nuclide without interference from the other nuclide. This determination is left to the user, however, and no specific claims regarding dual nuclide uses are being made. Due to the absence of new intended uses, it follows that the overall safety and effectiveness of the gamma camera system is not changed by this program.

- **Comparison of technological characteristics**

There is no change to the technology of the host device when the optional program Scatter Correction Volume, or T.E.W., is applied. This product is computational only and does not affect the physical characteristics of the host device. Determination of and correction for Compton-scatter effects are well understood and documented in peer-reviewed scientific publications.