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IX. SAFETY AND EFFECTIVENESS SUMMARY

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Premarket Notification [510(k)] Summary

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Summary prepared on:	July 8, 1996
Proprietary Name:	SEQUENTIAL SAMPLE MULTI-PHOTON DETECTOR (SSMPD)
Common/Usual Name:	Gamma Scintillation Counter
Classification Name:	Counter (Beta, Gamma) For Clinical Use
Substantial Equivalence:	The SSMPD is substantially equivalent in specifications and principles of operation to the Gamma 5500 Counting System (originally listed as Gamma 4000 Scintillation Counter), 510(k) Number: K770088, manufactured by Beckman Instruments, Inc., Scientific Instruments Division, Irvine, California 92713.
Description:	The SSMPD is a twelve sample, bench-top gamma radiation counter that can be used to measure counts per minute and calculate disintegrations per minute emitted by multi-photon emission isotopes, including ^{125}I. In volumes of 0.05 to 2.0 mls contained in 12 mm x 75 mm or 13 mm x 100 mm sample tubes disintegrations are measured over the range of 1 to 10^6 dpms. The sample tubes must be capped to minimize the possibility of contaminating the detector chamber. The full detector assembly is a twin detector system consisting of two scintillator crystals--each coupled to a high resolution planar photomultiplier. The entire detector is encased in a

composite lead-tin-copper shield to minimize environmental background. In addition to permitting efficient counting of gamma emitters, the sample holder acts as a separator to reduce crosstalk within the twin scintillator detector assembly.

The complete SSMPD system is comprised of a standalone SSMPD connected directly to a personal computer (PC) configured with SSMPD read-out electronics, MPDATA™ control and data logger software, and optionally, a printer.

Intended Use:

The SSMPD is intended as a general use clinical laboratory gamma radiation counter. The SSMPD is designed for use by operators qualified to measure gamma-ray emissions from radiolabelled reagents within particular energy bands or energy regions of interest (ROI) as part of diagnostic radioassay or radioimmunoassay methods. The standard quantitative units of measure reported are the measured count per minute (cpm) and the calculated disintegrations per minute (dpm).

Device Comparison:

Both the SSMPD and the Gamma 5500 Counting System utilize a 2" inorganic scintillating crystal, a photomultiplier tube (PMT), various electronic systems to amplify, scale, and analyze pulse heights, and a variety of output formats and devices for display of results to quantify gamma emissions in a sample.

However, the SSMPD uses two identical $CaF_2(Eu)$ scintillator crystals with PMT read-outs as a detector whereas the Gamma 5500 Counting System uses one NaI(Tl) scintillator crystal with PMT read-out. Both inorganic scintillator crystals have emission maximums that are well matched to the sensitivity of the bialkali photocathode PMTs used in the SSMPD and a refractive index that is close to that of most PMT windows and optical coupling compounds. The photoelectron yield of NaI(Tl) produces the highest signal of all known scintillators and is twice that of $CaF_2(Eu)$. However, the light yield of $CaF_2(Eu)$ is easily within an acceptable range of performance.

NaI(Tl) is susceptible to mechanical, thermal, and radiation damage. It is hydroscopic and colors over time and must be housed in a sealed environment. It is toxic. In addition, it is soft and cannot be machined easily. $CaF_2(Eu)$ is not

susceptible to mechanical, thermal, and radiation da
is transparent and insoluble in water and most
solvents, permitting radioactive samples in soluti
placed in direct contact with the crystal. It is non-
addition, it is hard and can be machined easily.

The SSMPD performs pulse shape as well as pul
analysis in software and hardware to increase the spe
pulse acceptance and rejection and lower the envir
background. The Gamma 5500 Counting System
pulse height analysis.

The SSMPD uses a 2" primary lead shield and a s
composite lead-tin-copper shield to minimize bac
events contributed by the lead itself. The Gamm
Counting System utilizes 1" of lead shielding
secondary composite shield.