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510(k) SUMMARY

Neoprobe Corporation's Model 1000 GEN 1C Portable Radioisotope Detector and Accessories

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: June 14, 1996

Name of Device and Name/Address of Sponsor

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Common or Usual Name

Radioisotope detector and accessories

Classification Name

Nuclear uptake probe and accessories

Predicate Device

Neoprobe Model 1000 GEN 1B Portable Radioisotope Detector and Accessories (K942580)

Intended Use

The Neoprobe® Model 1000 GEN 1C Portable Radioisotope Detector is an electronic device intended to detect and quantify gamma radiation. The GEN 1C is indicated for external and intraoperative detection of radioactivity in body tissues or organs in medical procedures where gamma emitting isotopes are administered.

Technological Characteristics and Substantial Equivalence

Device Description

The Neoprobe® Model 1000 GEN 1C Portable Radioisotope Detector ("Model 1000") consists of a microcomputer-based control unit, a cadmium zinc telluride gamma ray detector probe, a cable used to connect the probe to the control unit, a check source containing a known quantity of ^{129}I, and a chrome-plated Teflon-lined lead noise adjustment fixture used for periodic verification that the system continues to meet factory calibration readings. The detector probe is available in two sizes: (1) a detector probe with a 19 mm external diameter and a detector diameter of 15 mm; and (2) a detector probe with an 11 mm external diameter and a detector diameter of 7 mm. Optional accessories include a detector probe collimator and a detector probe shield.

Safety and Effectiveness

The GEN 1C is substantially equivalent to its predecessor, the Model 1000 GEN 1B, which received premarket clearance in 1995 (K942580). The GEN 1C is identical to the predicate device in general intended use, design, and principle of operation. The only differences between the GEN 1C and the predicate device are the use of a single-piece aluminum probe cap rather than a probe cap comprised of multiple parts, addition of a smaller (11 mm) detector probe, and use of a two millimeter radioactive

encapsulated area (check source) with the existing 19 mm probe and with the 11 mm detector probe. These minor differences raise no new issues of safety or effectiveness because the modified device continues to perform identical functions in the same manner as the predicate device.

Performance Data

Neoprobe has conducted laboratory studies to demonstrate the functional equivalence of the 11 mm GEN 1C probes to the predicate Model 1000 GEN 1B probe. These tests included: (1) a comparison of the counting efficiencies of six randomly selected 11 mm GEN 1C probes using a calibrated source of ^{129}I; (2) measurement of the counting efficiency of a representative probe as a function of probe-to-source distance for ^{125}I, ^{111}In, and ^{99m}Tc; and (3) measurement of the spatial resolution of the probe with and without collimation for the three nuclides. In summary, the counting efficiency of the 11 mm GEN 1C probes was found to be functionally equivalent to the counting efficiency of the predicate 19 mm Model 1000 GEN 1B probe.