

K971167

510(k) SUMMARY

JUN 26 1997

Neoprobe Corporation's Model 1500
Portable Radioisotope
Detector and Accessories

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

Submitter

Neoprobe Corporation
425 Metro Place North
Suite 400
Dublin, OH 43017-1367

Contact Person

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Director of Regulatory Affairs
Neoprobe Corporation
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Date Prepared: March 28, 1997

Name of Device and Name/Address of Sponsor

Neoprobe Model 1500 Portable Radioisotope Detector and Accessories

Neoprobe Corporation
425 Metro Place North
Suite 400
Dublin, OH 43017-1367
Phone: (614) 793-7500
Facsimile: (614) 793-7520

Common or Usual Name

Radioisotope detector and accessories

Classification Name

Nuclear uptake probe and accessories

Predicate Devices

Neoprobe Model 1000 GEN 1C Portable Radioisotope Detector and Accessories (K962319).

CareWise C-Trak Biopsy System (K922117)

Intended Use

The Neoprobe® Model 1500 Portable Radioisotope Detector is an electronic device intended to detect and quantify gamma radiation. It is indicated for external and intraoperative detection of radioactivity in body tissues or organs, such as bowel, bone, lymphatics, and red blood cells, where radiopharmaceuticals are administered.

Device Description

The Neoprobe® Model 1500 Portable Radioisotope Detector ("Model 1500") consists of (1) a microcomputer-based control unit; (2) a 12 mm collimated detector probe tip, a 12 mm non-collimated detector probe tip, and a 19 mm non-collimated probe tip, all of which are reusable, steam sterilizable and contain a cadmium zinc telluride crystal gamma ray detector; (3) a disposable sterile probe handle with an attached polypropylene cable; (4) a check source disk containing a known quantity of ^{129}I ; and (5) a chrome-plated Teflon-lined lead noise adjustment fixture used for periodic verification that the system continues to meet factory calibration readings.

Safety and Effectiveness

The Model 1500 is substantially equivalent to the Model 1000 GEN 1C, which received premarket clearance in 1996 (K92319). This submission covers modifications to the device since the Model 1000 GEN 1C received premarket clearance. These modifications include: (1) a modified control unit, (2) a disposable detector probe handle with attached cable, (3) a 12 mm noncollimated reusable, steam sterilizable detector probe tip, (4) a 12 mm collimated reusable, steam sterilizable reusable detector probe tip, and (5) a 19 mm noncollimated reusable, steam sterilizable detector probe tip. These modifications are intended to facilitate rapid and efficient probe interchangeability and to offer more options to the user.

Neoprobe has conducted laboratory studies to demonstrate the functional equivalence of the Model 1500 12 mm reusable, steam sterilizable non-collimated and collimated detector probe tips to the cleared Model 1000 GEN 1C 11 mm, EtO sterilizable detector probe. The tests performed on the cleared 11 mm and the new 12 mm collimated and non-collimated probe tips included measurement of the counting efficiency as a function of probe to source distance for ^{125}I , ^{111}In and

^{99m}Tc, and measurement of the spacial resolution of the probe tip with and without collimation for the three nuclides.

The results obtained with the cleared 11 mm probe and the new 12 mm probe tips demonstrate that the two types of detector probes are functionally equivalent except for the change in count rate that is predicted from the change in dimensions of the crystal. In terms of counts per second per unit, area of detector surface were the same for both the 11 mm and the 12 mm detector probe tips. The collimated and non-collimated versions of the reusable, steam sterilizable detector probes can be used interchangeably with the Neoprobe® 1500 control unit with the same disposable handle, without adjustments.

Neoprobe has submitted in previous 510(k) notifications (including K942580 and K864263) literature in support of the indications for use for which the company is seeking clearance in this submission. Specifically, literature has been supplied to FDA on the use of various radiopharmaceutical compounds and detector probes for intraoperative identification of areas with increased radionuclide concentration to support the use of Neoprobe's device during ischemic bowel, bone (osteoid osteoma), thyroid and colon applications. In addition, this 510(k) notice includes literature that supports the use of Neoprobe's Model 1500 for detection of radioactivity in lymphatics.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Susan Tiedy-Stevenson, M.S.
Director, Regulatory Affairs
Neoprobe Corporation
425 Metro Place North, Suite 400
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Re: K971167
Neoprobe® Model 1500 Portable
Radioisotope Detector and Accessories
Dated: March 28, 1997
Received: March 31, 1997
Regulatory Class: I
21 CFR 892.1320/Procode: 90 IZD

JUN 26 1997

Dear Ms. Tiedy-Stevenson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971167

Device Name: Neoprobe Model 1500 Portable Radioisotope Detector

Indications For Use:

The Neoprobe Model 1500 Portable Radioisotope Detector is an electronic device intended to detect and quantify gamma radiation. It is indicated for external and intraoperative detection of radioactivity in body tissues or organs, such as bowel, bone, lymphatics, and red blood cells, where radiopharmaceuticals are administered. For proper use and limitations of the Neoprobe Model 1500 refer to the product labeling.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971167

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____