

AUG 25 1998

K982442

**510 (k) SUMMARY**

Care Wise Medical Products Corporation's (Care Wise)  
C-Trak® Automatic Analyzer and Accessories

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

Care Wise Medical Products Corporation  
700-A East Dunne Avenue  
Morgan Hill, CA 95037

Contact Person

Robin A. Wise, Jr.  
President  
Care Wise Medical Products Corporation  
Phone: (408) 779-5531  
FAX: (408) 779-3185

Date Prepared: July 28, 1998

**Name of Device and Name/Address of Sponsor**

C-Trak® Automatic Analyzer

Care Wise Medical Products Corporation  
700-A East Dunne Avenue  
Morgan Hill, CA 95037  
Phone: (408) 779-5531  
FAX: (408) 779-3185

**Common or Usual Name**

Portable Radioisotope Detectors and Accessories

**Classification Name**

Nuclear Uptake Probe and Accessories

## Predicate Devices

NeoProbe 1000 and 1500 Analyzers and accessories currently marketed by the NeoProbe Corporation of Dublin, Ohio (K971167)

Care Wise C-Trak<sup>®</sup> Biopsy System (K922117)

Care Wise OncoProbe II<sup>™</sup> Analyzer (K896588)

## Intended Use

The intended use of the device here in question, i.e. the Care Wise C-Trak<sup>®</sup> Automatic Analyzer, remains unchanged from the intended use of prior predicate Care Wise and other portable radioisotope detectors. The Care Wise C-Trak<sup>®</sup> Automatic Analyzer is designed - as are all similar devices - to detect and quantify nuclear 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 Care Wise C-Trak<sup>®</sup> Automatic Analyzer consists of a battery-powered analyzer designed to operate a hand held probe, display the data from the detected radiation, and display and control the system's operating parameters.

## Safety and Effectiveness

Comprehensive shielding of high voltage sites within the instrument and operation only from internal batteries eliminate the possibility of significant electrical current leakage to patient or user under normal operating conditions. The C-Trak<sup>®</sup> system's electrical safety is greatly enhanced by the fact that the system is not designed or manufactured to be connected to an AC power line or any other type of external power supply. The system has been designed and manufactured for safe operation in an operating room environment, as long as flammable anesthetic gasses are not used.

Care Wise Medical Products Corporation believes that the C-Trak<sup>®</sup> Automatic Analyzer is substantially equivalent not only to each of its other analyzer products but also to products marketed before the passage of the Medical Amendments of May 28, 1976 and to other products such as the NeoProbe 1000 and 1500 Analyzers currently marketed by the NeoProbe Corporation of Dublin, Ohio. Documentation for this opinion is found on page 65A of Volume 17 of the Journal of Nuclear Medicine, January 1976, enclosed as Attachment V of this application and in NeoProbe promotional literature enclosed in Attachment VI. We intend to market both this and previously cleared technologies.



AUG 25 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Robin A. Wise, Jr.  
President  
Care Wise Medical Products Corporation  
PO Box 1655  
Morgan Hill, CA 95038-1655Re: K982442  
C-Trak Automatic Analyzer  
Dated: July 13, 1998  
Received: July 14, 1998  
Regulatory class: I  
21 CFR 892.1320/Procode: 90 IZD

Dear Mr. Wise:

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/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

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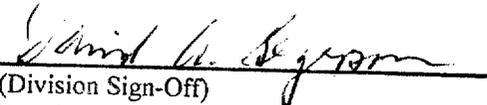
510(k) Number (if known): K982442Device Name: C-Trak Automatic Analyzer

## Indications For Use:

The intended use of the device here in question, i.e. the Care Wise C-Trak Automatic Analyzer, remains unchanged from the intended use of prior predicate Care Wise and other portable radioisotope detectors. The Care Wise C-Trak Automatic Analyzer is designed as are all similar devices- to detect and quantify the nuclear 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K982442

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use 

(Optional Format 1-2-96)