

OCT 29 1999

K992560

MAPS 10000
Web Link Medical
510(k) Premarket Notification

Appendix IX, 510(k) Summary of Safety and Effectiveness Data
Page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

- A. Submitted By: Web Link Medical
7720 Crosby Drive
Lone Tree, Colorado 80124-8966
Tel: (303) 790-8956
Fax: (303) 790-8958
- Contact Person: Mr. Chris Barlow at address above
- B. Device Trade Name: MAPS 10000
Common Name: Gamma Camera Systems
Classification Name: Emission Computed Tomography System
- C. Predicate Device: Sopha Medical Sophy NXT
GE Medical Systems Genie System

D. Device Description:

The MAPS 10000 is designed to acquire nuclear images as well as provide image display and processing, database utilities, and archiving utilities of nuclear imaging studies obtained using compatible existing acquisition software (subsystem) and gamma cameras. It is designed to be compatible with networked gamma camera and analogue camera systems using a windows-based operating system.

MAPS 10000 includes a software program used to archive new nuclear imaging studies on a local disc drive or networked disc drive, to perform file management tasks on existing patient studies and data files (select, protect, copy, move, delete, and print); to import foreign patient studies and data; to display and process studies and data files; and to run pre-set and user-defined image protocols.

E. Indications for Use:

The MAPS 10000 is intended to acquire, process, display and maintain nuclear imaging studies obtained using compatible gamma camera systems.

F. Technological Comparison:

The MAPS 10000, Sopha Sophy NXT, and GE Medical Systems Genie System have similar indications for use and overall function and they perform similarly with respect to data acquisition, processing, display and archiving.

II. Testing

Images were acquired, processed, and displayed using MAPS 10000.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1999

Chris Barlow
Vice President, Engineering
Web Link Medical
7720 Crosby Drive
Lone Tree, Colorado 80124

Re: K992560
MAPS 10,000 Gamma Camera System
Dated: August 2, 1999
Received: August 2, 1999
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Barlow:

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 legally marketed predicate 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K992560

Device Name: MAPS 10000

Sponsor Name: Web Link Medical

Indications For Use:

The MAPS 10000 is a nuclear medicine software package intended to acquire, process, display and maintain nuclear imaging studies obtained using compatible gamma camera systems.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use



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

510(k) Number K992560