

FEB 13 1998

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K974444

Summary of Safety and Effectiveness

for the

NumaStation
Numa, Incorporated

9.0 Introduction

This document is intended to be in accordance with the Safe Medical Devices Act of 1990 providing a summary of the information used to determine safety and effectiveness of the NumaStation nuclear medicine data acquisition system.

9.1 Substantial Equivalence

The NumaStation has been shown to be safe and effective because of its substantial equivalence to a predicate device: the Gamma 600t (K923736) from Strichman Medical Equipment, Incorporated.

- In both products the acquisition hardware is a microprocessor-based system and is separate from the host personal computer. This design is used to insure that integrity of the time-critical aspects of the data acquisition (time marks and ECG gate pulses) is kept independent of the personal computer operating system.
- Both the NumaStation and the Gamma 600t use simple, window-based GUIs to provide the nuclear medicine technologist with a comfortable work environment that insures reliable use of the system.
- The intended use of the NumaStation is as a conduit for nuclear medicine data. After acquisition of the data on the NumaStation, it is transferred through a variety of possible connectivity options to a third party workstation for processing. The Gamma 600t has similar third party connectivity designed in as well.

9.2 EMC Test Results

The following are the test results for the EMC testing per EN60601-1-2 and the NEMA testing per NU 1-1994.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

Kurt N. Larson
President
Numa, Inc.
10 Northern Boulevard, Unit 12
Amherst, NH 03031

Re: K974444
NumaStation (Nuclear Medicine Data Acquisition Computer)
Dated: November 18, 1997
Received: November 25, 1997
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Larson:

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 requirement, 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/dsmmain.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): K974444

Device Name: NumaStation

Indications For Use:

The NumaStation is a stand-alone computer interface that connects to third party gamma cameras and acquires data and transfers that data to a processing computer; it is used in planar and whole-body and SPECT imaging.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ferguson

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

510(k) Number K974444

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use