

K993893

FEB 10 2000

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510(k) SUMMARY

1. Submitter Information:

1.1 Submitter
MEDX Incorporated
3456 N. Ridge Ave., #100
Arlington Heights, IL 60004
Phone: (847) 463-2020
FAX (847) 463-2019

1.2 Manufacturing Facility
MEDX Incorporated
3456 N. Ridge Ave., #100
Arlington Heights, IL 60004

1.3 Contact:
Floyd Rowan

1.4 Date: November XX, 1999

2. Device Name

2.1 Tomographic Gamma Camera Systems

2.2 Classification Name: Camera, Scintillation (Gamma)
Classification Number: 901YX

2.3 Classification Name: Camera Tomographic Nuclear
Classification Number: 90JWM

2.4 Trade/Proprietary Name: MEDX InteCam™ Interface

2.5 Predicate Device: G.E. Starcam 4000
(DC K904174)

2. Device Description

3.1 Function

The NuQuest™ Nuclear Medicine Computer together with the MEDX InteCam™ Interface is used to acquire data from nuclear medicine gamma cameras. The data consists of a representation of

the x coordinate and y coordinate of the position and optionally a signal representing the energy of a gamma ray emitted from the decay of radioisotopes injected into a patient. The position of the decay is calculated (a ray from the event to the detector) by the gamma camera. The positions of a large number of decay events are used to form an image of the location of the radioactive material.

This image was originally produced by using photographic film exposed by a Cathode Ray Tube (CRT). A flash of light was produced on the CRT in the proper x,y location of the event. A large number of events produced an image on the film.

The substitution of a computer for the film allowed immediate viewing of the image, a more accurate rendering of the image since the non-linearities present in film were removed, and the capability for quantitative analysis of the data.

This image acquired can be displayed on a computer monitor or transferred to photographic film for review. The collection of data at multiple detector positions allows three dimensional information to be obtained by tomographic means. The computer is then used to reconstruct slices, or two dimensional views, of the data viewed from any angle or orientation.

The computer can also be used to obtain quantitative information such as the number of counts in a particular area of the image, or the rate of change of counts in an area of the image with respect to time.

Unlike most other diagnostic imaging devices (MR, CT, ultrasound), nuclear medicine devices emit no radiation, but rely on decay events from radioisotopes injected into a patient by a licensed technologist or physician.

3.2 Scientific Concepts

Diagnostic Nuclear Medicine began in early 1950's with the availability of short half-life radioisotopes. Isotopes such as I131 were injected into the patient and were selectively taken up by organ systems such as the thyroid. Measurement of the resulting

radioactivity in the organ provided information on both the size of the organ and the relative amount of isotope taken up.

Nuclear Medicine cameras work on a principle similar to television cameras. A collimator (lens) "focuses" gamma rays on a scintillation crystal. The scintillation crystal converts the gamma rays into light. Photomultiplier tubes are then used to convert the light into an electrical signal proportional to the energy of the detected gamma ray. Early instruments used a single hole lead collimator and detector that was moved in a raster pattern forming a 2-D image of the organ of interest. In the late 1950's methods were developed for directly obtaining a 2-D image by using a large crystal with multiple photomultiplier tubes and electronically calculating the position and energy of the gamma event. Two dimensional projections collected at many positions can be mathematically combined to yield a three dimensional representation of the data. This principle of tomographic reconstruction was discovered early in this century, but it was not until the advent of high speed digital computer that the technique could be successfully applied in diagnostic imaging first to CT then to Nuclear Medicine and MRI.

- 3.3 Nuclear Medicine is currently of great interest because of its high contrast, and relatively low cost per study. The ability to attach isotopes to substances that are selectively taken up by specific tissue types can provide very high contrast between the tissue and organ of interest and surrounding tissue. This has tended to compensate for the relatively poor spatial resolution of Nuclear Medicine compared to other modalities such as MRI.

In addition the uptake and clearing of the radioisotopes can be observed temporally, providing an indication of the biological activity of the tissue. This is important when attempting to determine tissue viability, or finding areas of abnormal activity such as cancerous tissue.

4.0 Device Intended Use:

- 4.1 The intended uses of the MEDX InteCam™ Interface and the NuQuest Nuclear Medicine Computer are the acquisition, processing, display and analysis of planar and SPECT nuclear

medicine images of all organ systems using approved radiopharmaceuticals.

5.0 Device Technological Characteristics:

- 5.1 The characteristics of the MEDX InteCam™ Interface when used with the NuQuest™ Nuclear Medicine Computer compare substantially with the predicate device, in both materials used, technology applied, and functional methodology. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category, and performs as well as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Floyd R. Rowan
Executive Vice President
Medx, Incorporated
3456 N. Ridge Ave. #100
Arlington Heights, IL 60004

Re: K993893
MEDX InteCam™ Interface
Dated: November 15, 1999
Received: November 16, 1999
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Rowan:

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

510(k) Number (if known): K993893

Device Name: MEDX InteCam™ Interface

Indications For Use:

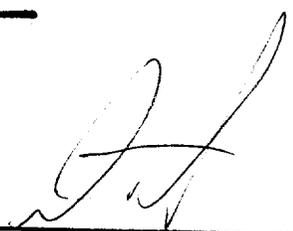
The intended uses of the MEDX InteCam™ Interface accessory together with the NuQuest™ Nuclear Medicine Computer are the acquisition, processing, display and analysis of planar and SPECT nuclear images of all organ systems using approved pharmaceuticals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)



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

510(k) Number K993893