

MAY 28 1997

Appendix VII

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

This Summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information

A. Submitted By: DIGIRAD Corporation
7408 Trade Street
San Diego, CA 92121-2410

Contact Person: Clinton L. Lingren

B. Classification Name: Scintillation (gamma) camera
Common/Usual Name: Gamma Camera
Trade Name: Notebook Imager™

C. Predicate Devices:

Table with 3 columns: Sponsor, Product, 510(k) No.
Rows: ADAC Transcam K921296; ELSCINT APEX SPX-4 ~~K961019~~ unknown; SCINTICOR SIM 400 K885054

D. Device Description:

The Notebook Imager™ system is a gamma camera which consists of an Imaging Head, an Arm and Cart assembly, and SITCO Nuclear Medicine software. The computer consists of a PC, Video Display Terminal, Keyboard, optional Printer and processing Software. The Imaging Head consists of a two-dimensional array of room-temperature, solid-state gamma-ray detectors with readout circuitry for constructing planar images of the emission from radiopharmaceuticals. This array consists of from 1 to 64 identical one-inch-by-one-inch imaging modules, each containing 64 (8x8) cadmium-zinc-telluride (CZT) semi-conductor detector elements mounted on a multichip submodule. The multichip submodule provides amplification of the input signals and identifies the address of the detector element in which each incoming photon is absorbed.

E. Intended Use:

The Notebook Imager™ is a gamma camera system which is intended for use in the generation of clinical images in Nuclear Medicine applications. Specifically, the Notebook Imager™ is intended to image the distribution of radionuclides in the body. In so doing, the system produces images depicting the anatomical distribution of radioisotopes within the human body for interpretation by authorized medical personnel.

F. Substantial Equivalence:

The Notebook Imager™ has the same intended use, uses the same principle of radiation detection, and has very similar performance characteristics as the predicate devices; the ADAC Transcam, k921296, the Elscint APEX SPX-4, ~~k901019~~ and the SCINTICOR SIM-400, k885054. The main difference is that the Notebook Imager™ uses CdZnTe semiconductor detector elements, which eliminate the conventional NaI crystal, the PMTs, and, as a result, most of the volume and weight of those camera heads and improves substantially the spatial resolution. When compared to the conventional camera system, these changes will have either no effect on the patient's safety, or rather decrease the risk to the patients, because of the reduced weight of the detector.

II. Clinical Tests:

No clinical testing was necessary.



Clinton L. Lingren  
Regulatory and Patent Liaison Officer  
DIGIRAD  
7408 Trade Street  
San Diego, CA 92121-2410

MAY 28 1997

Re: K961104  
Notebook Imager™ (Gamma Camera)  
Dated: February 26, 1997  
Received: February 27, 1997  
Regulatory Class: I  
21 CFR 892.1100/Procode: 90 IYX

Dear Mr. Lingren:

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): K961104

Device Name: NOTEBOOK IMAGER

Indication For Use: **For Nuclear Medicine Imaging Device**

	<u>Yes</u>	<u>No</u>	<u>Energy Range (KeV)</u>
A. Planar imaging	<u>X</u>	<u>  </u>	<u>30-300</u>
B. Whole Body imaging	<u>  </u>	<u>X</u>	<u>  </u>
C. Tomographic imaging (SPECT) for non-Positron emitter	<u>  </u>	<u>X</u>	<u>  </u>
D. Positron imaging by coincidence	<u>  </u>	<u>X</u>	<u>  </u>
E. Positron imaging without coincidence	<u>  </u>	<u>X</u>	<u>  </u>
F. Other indication(s) in the device label, but not included in above list	<u>To image the distribution of radionuclide in the human body.</u>		
	<u>  </u>		
	<u>  </u>		

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use   

David A. Benjamin  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K961104