

DEC - 3 1999

K992992

## 510(k) Summary

**Date:** September 3, 1999

**Submitter's Name:** Toshiba America Medical Systems, Inc.  
**Submitter's Address:** P.O. Box 2068, 2441 Michelle Drive,  
Tustin, CA 92781-2068

**Submitter's Contact:** Diana Thorson, Regulatory Affairs Specialist,  
(714)730-5000, Extension 4121

**Device Proprietary Name:** Automatic Image Registration Software, Model NSFU-050A  
**Classification Name:** Emission Computed Tomography System  
**Common Name:** Gamma Camera Option  
[Fed. Reg. No. 892.1200, Pro. Code: 90 KPS]

**Predicate Devices:** Toshiba GMS-5500A/UI Nuclear Medicine Image Processor  
(K931297)  
ADAC Image Fusion and Review System (K973233)

**Reason for Submission** New option for existing product

### Description of this Device:

The Automatic Image Registration Software, Model NSFU-050A is a software option for the Toshiba GMS-5500A/UI Nuclear Medicine Medical Image Processor. The software matches the position and size of two tomographic images acquired for the brain of the same patient and superimposes them for display.

### Summary of Intended Uses:

This software is designed to be used in combination with the Toshiba GMS-5500A/UI Nuclear Medicine Medical Image Processor. The software matches the position and size of two tomographic images acquired for the brain of the same patient and superimposes them for display. Nuclear medicine, CT, and MRI images can be processed using this software. This software can be used to perform registration between images of two different modalities and superimpose them. This device employs no intended uses that are not in cleared devices already found in the marketplace.

### Technological Characteristics:

The technological characteristics of this device are the same as that of the predicate devices. Multimodality image fusion is well understood and is documented in peer reviewed scientific publications.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Diana Thorson  
Regulatory Affairs Specialist  
Toshiba America Medical Systems, Inc.  
2441 Michelle Drive  
P.O. Box 2068  
Tustin, CA 92781-2068Re: K992992  
Automatic Image Registration Software  
Model NSFU-050A  
Dated: September 3, 1999  
Received: September 7, 1999  
Regulatory class: II  
21 CFR 892.1200/Procode: 90 KPS

Dear Ms. Thorson:

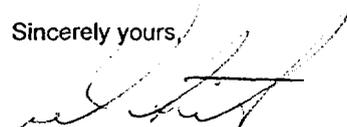
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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): K992992

Device Name: Toshiba Image Registration Software, Model NSFU-050A

**Nuclear Medicine Device**

**Indications For Use:** To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

		YES	NO	Energy Range (keV)
A.	Planar Imaging		X	
B.	Whole Body Imaging		X	
C.	Tomographic Imaging (SPECT) for non Positron Emitter	X		50-400
D.	Positron Imaging by Coincidence			
E.	Positron Imaging without Coincidence		X	
F.	Positron Whole Body Imaging by Coincidence		X	

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

David G. Syron  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT, and Radiological Devices

(Optional Format 1-2-96)

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