

July 1, 1999

Gary W. Enos
Hitachi Medical Corporation of America
Nuclear Medicine Products Division
9177 Dutton Drive
Twinsburg, OH 44087

Dear Mr. Enos:

As requested, we are returning your application for the registry of a sealed source and device evaluation. If you have any questions or need further assistance, please feel free to contact me at (301) 415-8140.

Sincerely,

TSI

Traci Kime, Registration Specialist
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

DISTRIBUTION:

NEO-2 SSD-1 *TSI*

1MNS r/f

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OFC	MSiB								
NAME	<i>TSI</i> TKime								
DATE	7/1/99								

OFFICIAL RECORD COPY

9907070374 990701
PDR RC *
SSD PDR

REQUEST FOR A SEALED SOURCE OR
DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN
Mail Stop O-6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER Hitachi Medical Corporation of America		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> HQ <input type="checkbox"/> LFARB	
TELEPHONE NUMBER 330-405-3330	DATE 04/23/1999	TYPE OF ACTION REQUESTED (Check as appropriate)	
NAME OF APPLICANT Gary W. Enos, General Manager		<input type="checkbox"/> SOURCE REVIEW	<input checked="" type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)
MAIL CONTROL NUMBER(S)		<input type="checkbox"/> DEVICE REVIEW	
LETTER/APPLICATION DATE 04/23/1999	LICENSE NUMBER(S)	<input type="checkbox"/> CUSTOM REVIEW	NR-1075-D-101-S

COMMENTS
**Nuclear Medicine Products Division
9177 Dutton Drive
Twinsburg, OH 44087**

FOR SSSS USE ONLY			
REVIEWER Seung Lee	MODEL NUMBERS Convergence NUA	NUMBER ASSIGNED 99-28	
DATE RECEIVED 04/27/1999	DATE ASSIGNED 04/27/1999	DATE TO FEES 04/27/1999	

TYPE OF ACTION (Indicate the number of each type)			
<input checked="" type="checkbox"/> COMMERCIAL DISTRIBUTION (FORMAL)		<input type="checkbox"/> USE BY A SINGLE APPLICANT (CUSTOM)	
SOURCE (9C)	SOURCE (9A)	SOURCE (9D)	SOURCE (9B)
<input type="checkbox"/> NEW	<input type="checkbox"/> NEW	<input type="checkbox"/> NEW	<input type="checkbox"/> NEW
<input type="checkbox"/> AMENDMENT	<input checked="" type="checkbox"/> AMENDMENT	<input type="checkbox"/> AMENDMENT	<input type="checkbox"/> AMENDMENT
<input type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED (IF KNOWN)	<input type="checkbox"/> YES <input type="checkbox"/> NO

☒ OTHER (Specify)
Payment received 4/27/99 in the amount of \$3600.00 - Check #14977

	TOTAL NUMBER OF REVIEW HOURS	NOTES
	NUMBER OF DEFICIENCY LETTERS	
	NUMBER OF DEFICIENCY CALLS	

FOR FEE USE ONLY			
TYPE OF FEE APP		FEE CATEGORY <input checked="" type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D	
AMOUNT RECEIVED \$3600	CHECK NUMBER 14977	DATE OF CHECK 4/19/99	LOG May 99 / SS+PD
APPROVED BY SA			DATE OF RETURN 5/3/99
COMMENTS			

HITACHI SPECTRA**Digital**TM Series
CONVERGENCESM V**250****dSP** Digital Dual Detector
Gamma Camera System
with
NUASM
Non-Uniform Attenuation Correction

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NQ: NR-1075-D-101-S

DATE: April 22, 1999

DEVICE TYPE: Line Source Holder/Attenuation Correction Device

Hitachi Medical Corporation of America
Nuclear Medicine Product Division
9177 Dutton Drive, Twinsburg, Ohio
Registration: 1530450

a Division of

Hitachi Medical Corporation of America
660 White Plains Road
Tarrytown, N.Y. 10591
Registration: 2434710

Manufacturing Establishment Reference:

Hitachi Medical Corporation
1-1-14 Uchi Kanda, Chiyoda-Ku
Tokyo, Japan 101
Registration: 8030405

with
Manufacturing Processes
at

Hitachi Medical Corporation Kashiwa Works
2-1, Shintoyofuta, Kashiwa-shi
Chiba-ken, 277, Japan

For Inquiry Contact:

Gary W. Enos

(330) 405-3330 / Fax : (330) 405-3222