Guidance for Industry

Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems

Document issued on: December 3, 1998

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Radiological Devices Branch
Division of Reproductive; Abdominal; Ear, Nose, and Throat;
And Radiological Devices
Office of Device Evaluation

GRZAN

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Robert Phillips, Ph.D., Chief, Conventional and Therapeutic Radiological Devices Branch, HFZ-470, 9200 Corporate BLVD., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Andrew Kang, MD at (301) 594-5072 ext.148 or by e-mail at sak@cdrh.fda.gov.

Additional Copies

World Wide Web CDRH home page: http://www.fda.gov/cdrh/ode/2240.pdf, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number **2240** when prompted for the document shelf number.

Table of Contents

		Page
I.	**Purpose**	**5**
II.	**Scope**	**5**
III.	**Background**	**5**
IV.	**Regulatory Requirements**	**5**
V.	**The New 510(k) Paradigm**	**6**
A.	Special 510(k)	6
B.	Abbreviated 510(k)	6
VI.	**Standards for Emission Computerized Tomography (ECT) Devices**	**7**
A.	NEMA Performance Standards	7
B.	Other Standards	7
VII.	**General Information Required in a Premarket Notification**	**8**
A.	General	8
B.	Administrative	8
C.	Device Description	8
D.	Software	9
E.	Year 2000 Compliance	9
F.	Electrical, Mechanical Safety	9
G.	Labeling	9
VIII	**Single Photon Emission Computerized Tomography (SPECT)**	**11**
A.	Definition	11
B.	Device Description	11
C.	Comparison with the Predicate Device(s)	12
D.	Performance	12
E.	Hazard Analysis	12
F.	Clinical Images	13

VIII-1 511 keV Ultra-High Energy Collimators (UHEC) 13

A. Definition 13
B. Background 13
C. Device Description 13
D. System Performance 13
E. Comparison with the Predicate Device(s) 13
F. Mechanical Safety Data 14
G. Clinical Images 14
H. Labeling 14

VIII-2 Attenuation Correction Device (ACD) for SPECT 15

A. Definition 15
B. Device Description 15
C. Comparison with the Predicate Device(s) 15
D. Bench Tests 16
E. Hazard Analysis 16
F. Clinical Images 16
G. Additional Labeling 16

IX Positron Emission Tomography (PET) 17

A. Definition 17
B. Device Description 17
C. Bench Tests 18
D. Comparison with the Predicate Device(s) 19
E. Hazard Analysis 19
F. Clinical Images 19

X. Coincidence Imaging Device (CID) 20

A. Definition 20
B. Device Description 20
C. Other Information 20

XI. Nuclear Tomography Systems 21

A. Definition 21
B. Device Status 21

Appendix

1. Declaration of Conformity 22
2. 510(k) Summary/Statement Certification 23
3. Indications for Use Form 24
4. Premarket Notification Truthful and Accurate Statement 25

I. Purpose

The purpose of this guidance document is to provide a detailed description of the information that should be included in a premarket (510(k)) notification for an emission computed tomography diagnostic device or nuclear tomography system submitted to the Center for Devices and Radiological Health (CDRH). This information is an elaboration of the general requirements contained in 21 CFR 807.87.

II. Scope

The scope of this document encompasses Emission Computed Tomography Systems as defined in 21 CFR 892.1200 and Nuclear Tomography Systems as defined in 21 CFR 892.1310.

"An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron- emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data"

"A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from the other planes."

This includes Single Photon Emission Tomography (SPECT) imaging systems and their accessory devices, 511 keV Ultra-High Energy collimators (UHEC), Attenuation Correction Devices (ACD), Positron Emission Tomography (PET) imaging systems and their accessories, Coincidence Imaging Devices (CID), and Nuclear Tomography Systems (NTS) and its accessories.

III. Background

A number of legislative changes relating to the authority of the agency have occurred. These changes have resulted in the adoption of new regulations and administrative procedures by CDRH which affect the 510(k) process. The Safe Medical Devices Act of 1990 (SMDA) has resulted in New Good Manufacturing Practice (GMP) regulations requiring pre-production design controls, and several administrative requirements (Summaries of Safety and Effectiveness, and Statements of Indications for Use) have been added. The Food and Drug Administration Modernization Act (FDAMA) of 1997 and a re-engineering effort have resulted in the development of a new 510(k) paradigm, which incorporates alternative approaches to demonstrating substantial equivalence in premarket notifications. These approaches are intended to facilitate the marketing clearance of devices, such as SPECT or PET devices, for which recognized standards exist, and for cases in which the new device is a modification of a previously cleared product.

IV. Regulatory Requirements

Under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act of 1976, all Emission Computed Tomography (ECT) and their accessory devices may be cleared by 510(k) process, when the device shows substantial equivalence to the legally marketed predicate devices.

All Emission Computed Tomography devices and accessories are currently classified as Class II devices with a Product Code of 90-KPS. Nuclear Tomography Systems are classified Class II with a product code of JWM.

V. The New 510(k) Paradigm

On March 20, 1998 CDRH issued a document entitled "The New 510(k) Paradigm - Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". This document is available on the CDRH web site (http://www.fda.gov/cdrh/ode/parad510.html). In addition to the traditional 510(k), this document describes two alternatives, the "Special 510(k): Device Modification" and the "Abbreviated 510(k)".

A. Special 510(k)

The Special 510(k) is based on the requirement that manufacturers establish design controls in accordance with the SMDA and 21 CFR 820.30. A manufacturer uses the FDA guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" to decide if a device modification could be implemented without submission of a new 510(k). If a new 510(k) is needed, and if the modification does not affect the intended use of the device or the basic fundamental scientific technology, conformance with design controls may form the basis for clearing the application. Under this option, a manufacturer who is intending to modify a legally marketed Class II device would conduct the necessary verification and validation activities to demonstrate that the design output of the modified device meets the design requirements. Once the company has ensured the satisfactory completion of this process through a design review, a Special 510(k) may be submitted. While the basic content requirements for the submission are the same, this type of submission should also reference the cleared 510(k) and contain a "Declaration of Conformity" with design control requirements. In the Special 510(k) the manufacturer has the option of using a third party to assess conformance with design controls (refer to the paradigm document for details). Special 510(k)s are to be processed by the Office of Device Evaluation within 30 days of receipt by the Document Mail Center.

B. Abbreviated 510(k)s

The Abbreviated 510(k) is based on the use of conformance to voluntary standards in place of data review as the means by which the safety and effectiveness of Class II devices can be assured. Manufacturers may submit an Abbreviated 510(k) when FDA has recognized an individual or several voluntary standards that cover aspects of the new device. In addition to the required elements of a 510(k) as described in 21 CFR 808.87, Abbreviated 510(k) submissions should include information that describes how conformance to one or several voluntary standards, recognized by CDRH, have been used to address risks associated with the device, and a "Declaration of Conformity" to those standards. The "Declaration of Conformity" should provide the information listed in the paradigm. A third party may be used to assess conformance with these standards (refer to the paradigm document for details). The review of abbreviated 510(k)s is intended to be more efficient since they are not required to contain the experimental data from which conformance is determined.

VI. Standards for Emission Computed Tomography (ECT) Devices

The Food and Drug Administration Modernization Act of 1997 authorizes CDRH to recognize consensus standards established by national and international standards development organizations that may be used to satisfy identified portions of device review requirements. On February 19, 1998 CDRH issued a "Guidance on the Recognition and Use of Consensus Standards" which is intended to provide information relating to the recognition and use of national and international consensus standards. It is available on the CDRH web site (hhtp://www.fda.gov/cdrh/modact/k982.html), and describes how the agency will use information on conformance with recognized standards to satisfy premarket review requirements. It also describes the content of a declaration of conformity. In the case of 510(k)s, information on conformance with recognized standards might help establish the substantial equivalence of a new device to a legally marketed predicate in the areas covered by the standards. If a premarket notification contains declarations of conformity, this will in most cases eliminate the need to review the actual test data for those aspects of the device addressed by the standards. However, the results of testing are expected when the standard specifies a test method without the associated performance limits, as in the case of the NEMA standards discussed below.

A. NEMA Performance Standards

The NEMA standards NU 1and NU 2 are recognized by CDRH and thus may be used in Abbreviated 510(k)s for emission tomographic diagnostic devices. They provide standardized methods for measuring performance parameters for and gamma cameras (SPECT) and positron cameras (PET). To the extent possible, these methods should be utilized in traditional as well as abbreviated 510(k)s. The NEMA standards are:

NU 1 ---- Performance Measurements of Scintillation Cameras (1994)

NU 2 ---- Performance Measurements of Positron Emission Tomographs (1994)

It is important to recognize that the NEMA standards only prescribe standard measurement methods. They do not specify acceptable levels of performance or safety. Acceptable levels of performance are assessed by a comparison to previously cleared devices, on a case-by-case basis, depending upon intended use, and the substantial equivalence criterion.

B. Other Standards

Levels of electrical and mechanical safety parameters are addressed by other standards discussed below. These standards are also recognized by CDRH.

IEC 60601-1, International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC 60601-1-2, Requirements for safety; Electromagnetic Compatibility – Requirements and Tests

EN 1441 (1997), Medical Devices – Risk Analysis

UL 544, Standards for Medical, Dental Equipment, 3rd edition

UL 2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety (This is the UL version of IEC 60601-1).

NEMA PS3, DICOM (Digital Imaging and Communications in Medicine) (set includes PS3-1 through PS3-13) -- This standard specifies formats for the exchange of radiology and other medical images.

VII. General Information to be Submitted in a Premarket Notification

General information to satisfy 21 CFR 807.87 for premarket notification submissions is listed and discussed in detail below. This applies to all devices covered in this guidance along with the specific requirements listed under the specific device sections.

A. General

Name and address of manufacturer.
Establishment registration number (if not available, registration application should be submitted).
Name, title, phone number, fax number and E-mail of contact.
Trade name, model number, and common name of device.
Type of submission (special, abbreviated or traditional)
Classification and class of device (21 CFR 892.1200, class II), and product code (90-KPS)
Intended use (general purpose of device per 21 CFR 892.1200)
Applicable standards (e.g. NEMA, IEC or other standards).

B. Administrative Information

510(k) Summary of Safety and Effectiveness or Statement (see 21 CFR 807.92 and 807.93)
FDA Indications for Use Form (specific diagnostic use of device, i.e**.** the anatomical region and/or disease/condition which the device is intended to diagnose)
Truthful and Accurate Statement (see 21 CFR 807.87(j))
Declarations of Conformity to Consensus Standards (Abbreviated 510(k) only)
Declaration of Conformity to Design Controls (Special 510(k) only)

C. Device Description

Refer to each specific device section.

D. Software

Software used for ECT devices, in image acquisition, processing, creation of patient's database or image transmission, are of a moderate level of concern, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (CDRH, 1998)."

The following lists, in general, the software information that should be included is a submission:

- The level of concern
- A software description, including version number
- Device hazard analysis
- Software requirements specifications
- Architecture design chart
- Design specifications
- Traceability analysis
- Summary of the software life cycle development plan, including configuration management and maintenance activities)
- Description of Validation, Verification, and Testing activities at the unit, integration and system level. System level test protocol including pass/fail criteria and test results.
- Revision history log
- List of errors and bugs that remain in the device and an explanation how they were determined not to impact safety and effectiveness, including operator usage and human factors

E. Year 2000 Compliance

Until January 1, 2000, specify whether the device is Year 2000 compliant. Describe the method(s) used for making this determination.

F. Electrical, Mechanical Safety

Provide information to establish the safety (electrical, mechanical, thermal, etc.) of your device. This may be either a Declaration of Conformity to FDA recognized standard(s), data following an unrecognized standard together with a rationale for its use, or complete data and a description of the testing methodology.

G. Labeling

Following labeling recommendations apply to all Emission Computed Tomography (ECT) devices, in addition to the specific labeling recommendations discussed under the specific device sections. The labeling for a ETC device should consist of Essential Prescribing information (see "Medical Device Labeling --Suggested Format and Content, http://www.fda.gov/cdrh/ode/labeling.html#epi), specifications (i.e. a product data sheet), promotional material, and instructions for use (operator's manual).

1. Essential Prescribing Information (EPI) Consists of:

   a. a brief device description;
   b. intended use / indications;
   c. contraindications, warnings, precautions;
   d. adverse events;
   e. conformance to standards;
   f. operator's manual -- brief description
      i. maintaining device effectiveness
      ii. complete device description
      iii. directions for use
   g. summary of recommended quality control method(s); on daily, weekly, or quarterly bases;
   h. summary of recommended maintenance schedules for the equipment, including a designation of whether they should be performed by the user or company service personnel;
   i. summary of or reference to NRC requirements for radioisotope handling (when a radioisotope is installed in the device permanently or transiently for imaging purposes);
   j. references

2. Summary Specification Sheet

   Provide a listing of the device specifications.

3. Promotional Material (Product Data Sheet)

   Claims contained in the promotional material should be consistent with the statements in the FDA “Indications for Use” form.

4. Users Manual

   Complete instructions for the use of the device.

VIII. Single Photon Emission Computed Tomography (SPECT)

A. Definition

Single Photon Emission Computed Tomography (SPECT) devices are intended to detect gamma radiation events and produce tomographic images that reflect the distribution of a radiopharmaceutical in the body or individual organs. [Devices capable of detecting coincidence events of 511 keV photons are not included in this section; refer to Section C. Coincidence Imaging Devices (CID)].

B. Device Description

The device description should contain the following information.

1. A list of major components of the system and their purpose, including the number of the detector heads, gantry, patient's table, and acquisition and processing work station with related interfacing software.

2. A description of the basic design principles of gamma detection and image production methods used, the unique features of the system, and the similarities to, and the differences from the predicate device, in regard to the energy source, performance characteristics, and the patient's safety. (e.g., describe the type of crystal used, conventional NaI crystal vs. solid state semiconductor (CdTe) unit (or other type of crystals); the photomultiplier tubes (PMT), the image acquisition mode, the image processing method and algorithms, the interface software, the energy range of photon detection, the image storage and retrieval, the gantry design, collimators, patient's table, and a built-in radioactive scanning source housing, if there is one).

3. A description of the following:

   a. Detector ---- physical characteristics of the detector, including the shape and the size of a detector head, FOV, number of crystal, or other gamma detecting unit, and the thickness of the crystal, the shape and number of PMTs.
   b. System Gantry ----the physical dimensions, partial and overall weight, functional design, stability, mobility, safety features.
   c. Patient's table ---- the overall dimensions, design characteristics, material, weight limitation, safety features.
   d. Collimators ---- the number of collimators included, model numbers, weight of each collimator, collimator mounting accessories and safety features.
   e. Collimator storage and exchange cart ---- the collimator storage unit and the method of collimator exchange. (manual, automatic, etc).
   f. Image Acquisition and processing work station ----- the workstation, e.g.; integrated, acquisition or processing only, universal or domain.

g. Software; acquisition, processing, and networking ---- acquisition software, reconstruction methods; FBJ (filtered Back Projection), or iterative, processing software, 3rd party software, networking interface method,

h. Other accessory devices ----- display monitors, hand-held or wireless remote control unit, laser-positioning device, image storage and other hardware and software.

i. Functional characteristics, e.g.; simultaneous, dual isotope, triple window imaging, whole body capability, analog, or digital signal processing with ADC (Analog to Digital Converter), body contouring, etc.

4. Photograph(s) showing the front, side and top view(s) of the device and summary diagrams or drawings showing the dimensions of major parts and components and describing the connections between the various components.

C. Comparison of the New and Predicate Device(s)

A 510(k) submission is a comparison of a new device to a predicate to show that the two devices are substantially equivalent. Therefore, the sponsor must identify at least one class II legally marketed device to which equivalence is claimed and compare the device to the predicate in terms of design, performance, and functional and physical specifications. Any significant differences should be explained and a rationale given for substantial equivalence.

D. Performance

The performance characteristics of the system should be provided. These should include:

intrinsic spatial resolution in FWHM at the surface and at 10 cm;

spatial energy resolution;

spatial linearity;

flood field uniformity;

count rate sensitivity; and

isolation of the detector to background.

Performance test data should be obtained using a NEMA NU1 phantom or an equivalent, under the NEMA or equivalent performance standard test procedures. Describe, in detail, alternate methods and phantoms and provide a rationale for the acceptability of these alternates.

E. Hazard Analysis

In tabular form, summarize the potential hazards (electrical, mechanical, radiation, software, etc.) associated with the device and describe the methods used to mitigate them. (This is not needed if it is provided in the software section).

F. Clinical Images

Provide sample images from three clinical cases (may be from three different procedures), using the subject SPECT device.

VIII-1 511 keV Ultra-High Energy Collimators (UHEC) for SPECT

A. Definition

A 511 keV UHEC is an accessory device to a SPECT system that enables it to effectively detect and image 511 keV photons.

B Background

In January 1997,CDRH issued a letter announcing the agency's decision to allow 511 keV collimators to be cleared for market by the 510(k) process.

C. Device Description

Provide a description of the collimator including the hole diameter, septal thickness, hole length, number of holes, dimensions, detector shielding, collimator weight, the total weight of all collimators on the system (i.e. triple detector devices usually use three collimators, the collimator supporting mechanism, mechanical safeguards, collimator storage device and the collimator changing procedure.

D. System Performance

The performance characteristics of the system with the collimator(s) should be provided and include:

intrinsic spatial resolution in FWHM at the surface and at 10 cm;

spatial energy resolution;

spatial linearity;

flood field uniformity;

count rate sensitivity; and

isolation of the detector from background.

Performance test data should be obtained using a NEMA NU1 phantom or an equivalent, under the NEMA or equivalent performance standard test procedures. Describe, in detail, alternate methods and phantoms and provide a rationale for the acceptability of these alternates.

E. Comparison with the Predicate Device(s)

A 510(k) submission is a comparison of a new device to a predicate to show that the two devices are substantially equivalent. Therefore, the sponsor must identify at least one class II legally marketed device to which equivalence is claimed and compare the device to the predicate in terms of design, performance,

and functional and physical specifications. Any significant differences should be explained and a rationale given for substantial equivalence.

F. Mechanical Safety Data

1. Provide a detailed description and drawing of the collimator mounting assembly to the detector head for each model of camera system that the collimator is intended to fit. Provide the design safety factor of the mounting assembly that supports collimator weight.

2. Provide data showing that the system can safely support the weight of the collimator(s). Describe the test procedures used to determine this.

3. If upgrading an existing system to accommodate the 511 keV collimator(s), provide the results of and describe the test procedures used to ensure the safety of the old system with the new collimator(s) installed.

G. Clinical Images

Submit sample images from three different organs, such as brain, lung, and heart, obtained on each system used with the collimator.

H. Labeling

1. For an add-on collimator, for each system intended to be used with the collimator(s), provide the system name, model number, and list the performance specifications for the 511-keV collimator (see part D, this section).

2. Include a brief precautionary statement on the limited spatial resolution of the 511 keV collimator, such as the following.

"Caution: The minimum spatial resolution on this system using 511-keV collimator is __ mm. (Fill the blank with the device's measured resolution). The spatial resolution of 511 keV collimator is generally not as good as that of a typical PET imaging system."

3. Include a warning that the system should only be used with FDA approved radiopharmaceuticals.

VIII-2. Attenuation Correction Device (ACD) for SPECT

A. Definition

An Attenuation Correction Device for SPECT is an accessory intended to correct or minimize the distortion caused by false information in emission computed tomographic images due to overlying tissue or undesired scatter photons.

The indication statement should include the specific trade name of the ACD and the name and model number of the camera system(s) that the ACD is intended to be used with. The statement should also specify whether it includes scatter correction capability.

B. Device Description

1. Provide a description of the ACD including the method(s) of the attenuation correction (fan beam, parallel beam, or multiple line array, fixed or scanning beam(s)), the method of scatter correction (split energy windows (or triple energy windows, TEW) or pixel by pixel correction). It should also specify the number of the ACD devices in a system, and provide a detailed description of the components, acquisition methods (sequential or simultaneous acquisition of emission and transmission images), and the image reconstruction algorithm (such as; MLEM or OSEM, FBP, or iterative). Also include a description of transmission source, the source housing, the radiation and other safety features, and other physical, functional specifications of the device. The transmission source description should include the type of source (isotope), the amount of radioactivity, and descriptions of the source housing, safety features of the housing, the shutter, and shielding.

2. Submit a photograph, drawing, or diagram of the ACD, showing its dimensions, the source housing, the detector head and the connection with the ACD assembly. Describe of the material used, the design and the construction of the housing and comment on the related safety issues.

C. Comparison with the Predicate Device(s)

A 510(k) submission is a comparison of a new device to a predicate to show that the two devices are substantially equivalent. Therefore, the sponsor must identify at least one class II legally marketed device to which equivalence is claimed and compare the device to the predicate in terms of design, performance, and functional and physical specifications. Any significant differences should be explained and a rationale given for substantial equivalence.

D. Bench Tests

1. Radiation measurements

a. Provide the leakage radiation rates from source housing measured with the source in the "OFF" position. Describe the methods and equipment used to do these measurements or provide a declaration of conformity to a recognized methodological standard (e.g., NRC guideline for measurement of leak rate of a radioactive sealed source or NCRP Report 102). Leakage rates, less than 2 mGy/h (200 mrad/h) at 5 cm from the surface of the source housing, and less than 20 μGy/h (2 mrad/h) at 1 m from the source are acceptable range.

b. Provide an estimate of the patient radiation exposure dose from the transmission source for a typical clinical procedure.

3. Using NEMA NU 1, SPECT phantom or an equivalent phantom, provide comparison data and images with and without the use of ACD. Also provide comparison data for uniformity, attenuation map generation, and spatial resolution.

E. Hazard Analysis

In tabular form, summarize the potential hazards (electrical, mechanical, radiation, software, etc.) associated with the device and describe the methods used to mitigate them. (This is not needed if it is provided in the software section).

G. Clinical Images

Submit images from three clinical studies obtained with and without using ACD.

H. Additional Labeling

The source replacement procedure should be thoroughly described in the user's manual, including the wipe test procedure according to the NRC Guideline or equivalent.

IX. Positron Emission Tomography (PET) System

A Definition

Positron Emission Tomography (PET) devices are intended to detect, using coincidence detection circuitry, 511 keV gamma radiation events, and produce tomographic images that reflect the distribution of a positron emitting radiopharmaceutical in the body or individual organs.

B. Device Description

The device description should contain descriptions of the general design and functional characteristics of the system. It should include the device's trade name, model number, a list of components, a description of the physical, functional, and performance characteristics of each component, a description of the patient and user safety features, and the similarities and differences from the predicate device(s).

1. The following should be described in detail:

   a. Detector unit --- Descriptions should include the type of scintillator (NaI, BGO, CsF, LSO, etc.); the number, size, thickness of the scintillator and PMTs; and the cooling system. Provide the general or measured performance characteristics.

   b. Gantry System ---- Describe the physical and functional characteristics of the gantry; e.g., dimensions, design principles, whether it is a rotating ring gantry or multi-detector gantry system, and patient safety features.

   c. Patient table ---- Provide physical dimensions, functional characteristics, patient weight limitation, and safety features.

   d. Transmission source ---- Provide the name of the isotope and the amount of radioactivity. Provide a physical description of the source housing and a description of its safety features.

   e. Computer workstation and software ---- Describe the computer workstation, acquisition software, reconstruction algorithms (e.g., OSEM (Ordered Subset Expectation Maximization), FBJ (filtered Back Projection), iterative reconstruction, etc.), 3rd party software, networking software, and interfacing method.

   f. Other accessory devices ----- Describe display monitors, hand-held or wireless remote control units, laser positioning devices, image storage and other hardware and software.

4. Provide photograph(s) showing the front, side and top view(s) of the device and summary diagrams or drawings showing the dimensions of major parts and components and describing the connections between the various components.

C. Bench Tests

1. Radiation measurements

a. Provide the leakage radiation rates from source housing measured with the source in the "OFF" position. Describe the methods and equipment used to do these measurements or provide a declaration of conformity to a recognized methodological standard (e.g., NRC guideline for measurement of leak rate of a radioactive sealed source or NCRP Report 102). Leakage rates less than 2 mGy/h (200 mrad/h) at 5 cm from the surface of the source housing, and less than 20 uGy/h (2 mrad/h) at 1 m from the source are acceptable.

b. Provide an estimate of the patient radiation exposure dose from the transmission source for a typical clinical procedure.

2. System performance

The performance characteristics of the system should be provided and include:

intrinsic spatial resolution in FWHM at the surface and at 10 cm;

energy resolution;

transverse and axial resolutions

spatial linearity;

flood field uniformity;

the system sensitivity,

coincidence timing window,

coincidence dead time,

scatter fraction,

scatter correction method,

slice thickness,

count rate sensitivity; and

isolation of the detector from background.

Performance test data, should be obtained using a NEMA NU2 phantom, or an equivalent, under the NEMA or equivalent performance standard test procedures. Describe, in detail, alternate methods and phantoms and provide a rationale for the

acceptability of these alternates. Results should be reported in the same units as specified in the NEMA standard.

D. Comparison of the new and predicate device(s)

A 510(k) submission is a comparison of a new device to a predicate to show that the two devices are substantially equivalent. Therefore, the sponsor must identify at least one class II legally marketed device to which equivalence is claimed and compare the device to the predicate in terms of design, performance, and functional and physical specifications. Any significant differences should be explained and a rationale given for substantial equivalence.

.

E. Hazard Analysis

In tabular form, summarize the potential hazards (electrical, mechanical, radiation, software, etc.) associated with the device and describe the methods used to mitigate them. (This is not needed if it is provided in the software section).

F. Clinical Images

Provide sample images from three clinical cases using the submitted PET device.

X. Coincidence Imaging Devices (CID)

A. Definition

A Coincidence Imaging Device is a SPECT system, which is equipped with coincidence circuitry to allow the detection of coincident 511 keV photon events. The device can be operated in either single photon or coincident photon mode.

B. Device Description

1. Description of the non-coincidence part of SPECT system

Describe as a conventional SPECT system. Follow the guidelines described under Section A of the document titled Single Photon Emission Computed Tomography (SPECT).

2. Description of the coincident part of the SPECT system

Describe each component associated with coincidence detection. Describe the design principles of the device's coincidence detecting capability and discuss all the modifications, from the original SPECT system, built into the system to improve the functionality of coincidence imaging.

a. Detector system ---- Descriptions should include the type, size, and thickness of the scintillator; and the number and size of PMTs; the Constant Fraction Discriminator (CFD), scatter shields, axial filters, coincidence detection circuitry, and the timing device.

b. Performance specification of coincidence device ---- Provide the common performance specifications including spatial resolution (FWHM), system sensitivity, energy resolution, count rate performance, coincidence window, scatter fraction (%), count efficiency, coincidence dead time.

c. Coincidence enhancement methods applied ----- Describe the methods used to implement coincident imaging such as pulse shortening (pulse clipping), multiple trigger channels, dual energy windows, shortening the dead time, etc.

C. Other Information

Other information to be submitted -- device photographs, diagrams and drawings, bench tests, safety evaluation, hazard analysis, software, and clinical images -- are the same as for SPECT and PET Imaging Systems respectfully. Please follow the guidelines in Sections VIII, Single Photon Emission Computed Tomography (SPECT) and IX, Positron Emission Tomography (PET) of this guidance.

XI. Nuclear Tomography Systems

A. Definition

A nuclear tomography system (NTS) is a device intended to detect nuclear radiation in the body, using a scintillation (gamma) camera, and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from the other planes by means of synchronous motion of the camera collimator and the patient support assembly.

B. Device Review Process

The device covered by this section used mechanical motion synchronized between the camera collimator and patient table to create a tomographic effect with the image plane parallel to the patient table. Emission computed tomography superseded NTS as the method of choice for performing nuclear medicine tomography. The last submission for marketing approval for an NTS device was received in 1991. CDRH, therefore, regards NTS devices to be obsolete. There are no submission guidances available for this type of device.

Appendix 1

Declaration of Conformity

Voluntary Standards in 510ks

Reviewers should rely on a declaration of conformity to the recognized consensus standards if the declaration

- identifies the applicable recognized consensus standards and specifies those that were met;
- specifies, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below;
- identifies for each consensus standard any way(s) the standard may have been tailored or modified for application to the device under review, e.g., identifies which of an alternative series of tests were performed;
- identifies, for each consensus standard, any requirements that were not applicable to the device;
- specifies any deviations from each applicable standard that were applied (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70));
- specifies what differences exist, if any, between the tested device and the device to be marketed and justifies the use of test results in these areas of difference; and
- if a test laboratory or certification body was employed, provides the name and address of each laboratory or certification body that was involved in the determining the conformance of the device with the applicable consensus standards and a reference to any accreditation of those organizations.

Appendix 2

510(k) Summary/Statement Certification

Re: K_____

CHECK ONLY ONE:

☐ 1. **510(k) Summary**. Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

☐ 2. **510(k) Statement**. I certify that, in my capacity as

_____

of _____(company),

I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____

[Signature]*

_____

[Typed or Printed Name]

_____

[Date]

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

Appendix 3

Indications for Use Form

Page____of____

510(k) Number (if known):_____

Device Name:_____

Indications For Use:

(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)

(Optional Format 1-2-96)

GRZAN

Appendix 4

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

(as required by 21 CFR 807.87(j))

I certify that, in my capacity as _____
of _____(company name), I believe, to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.

_____ _____

(Signature)* *(Date)*

_____ _____

(Typed Name) *(510(k) number)*

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).