K081426

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

JUN - 4 2008

A. ***Submitter/ Contact Person***:

Philips Medical Systems (Cleveland), Inc.
595 Miner Rd.
Cleveland, OH 44143

Melinda Novatny
Tel: (440) 483-4255
Fax: (440) 483-2300

B. ***Device Trade Name***: NexStar Liftoff PET Application Software Suite

Common Name: PET Application Software

Classification Name: System, Emission Computed Tomography, (892.1200)

Device Class: 21CFR 892.1200, Class II

Product Code: 90 KPS

Classification Panel: Radiology

C. ***Date prepared***: April 11, 2008

D. ***Predicate Device***: GEMINI Raptor System (GEMINI TF) (K052640)

E. ***Performance Standards:***

No performance standards have been developed for process and display applications.

F. ***Intended Use***:

Software contained in the PET Application Suite process, analyze, display, and quantify medical images/data. The PET and CT images may be registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined metabolic and anatomical data at different angles. Trained professionals use the images in:

- The evaluation, detection and diagnosis of lesions, disease and organ function such as cancer, cardiovascular disease, and neurological disorders.
- The detection, localization, and staging of tumors and diagnosing cancer patients.
- Treatment planning and interventional radiology procedures.

The PET Application Suite includes software that provides a quantified analysis of regional cerebral activity from PET images.

Cardiac imaging software provides functionality for the quantification of cardiology images and datasets including but not limited to myocardial perfusion for the display of wall motion and quantification of left-ventricular function parameters from gated myocardial perfusion studies and for the 3D alignment of coronary artery images from CT coronary angiography onto the myocardium.

G. ***Device Description/ Comparison with Predicate Device***:

The NexStar Liftoff PET Application Software Suite (referred to as NexStar or Liftoff within the submission) is software used to process, analyze and display medical images and may be sold with Philips nuclear medicine PET/CT Systems or systems marketed by Philips. The PET Software Application Suite is a full suite of applications, including both review and processing.

The NexStar Liftoff PET Application Software Suite is basically the same as the processing and reconstruction software cleared with the predicate device (GEMINI TF, K052640), with the extension of Image Fusion Software to include Metabolic Analysis and Cardiac Realignment.

NexStar software is a Windows®-based suite of image display and processing applications and is deployable on hardware platforms, which meet the minimum requirements needed to run the software.

H. ***System Performance Test/ Summary of Studies***:

No performance standards have been developed for process and display applications.

I. ***Comparison to Predicate Devices:***

The basic differences in the system include the following:

- Deployment of software on hardware platforms meeting minimum level of requirements
- Enhancements to processing applications

In conclusion, the device is substantially equivalent to the predicate device based upon similar intended use, and technological comparison.

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K081426_ Third Party Organization: Underwriters Laboratories, Inc.
Third Party's Primary Reviewer(s): Jeff D. Rongero
ODE/OIVD Division: DRARD Branch/Team: Radiological Devices Branch
Section 2 – 510(k) Decision
Third party recommendation: SE √____ NSE ____ Other (specify): _____
ODE/OIVD final decision: SE √____ NSE ____ Other (specify): _____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	√		
b. Extent of pre-submission consultation with ODE/OIVD division			
c. Organization and format of review documentation	√		
d. Determination of 510(k) administrative completeness (screening review)	√		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	√		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	√		
g. Rationale for conclusions and recommendation	√		
h. Use of guidance documents and standards	√		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	√		
j. Scope of reviewer expertise and use of consulting reviewers	√		
k. Other (specify):			

Comments (explanation of ratings/issues): _____.

Section 4 – ODE/OIVD Assessor Information
Assessed by: Sunder Rajan_ Date: 28-May-2008 Tel. No.: 240 276 3968
Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

Philips Medical Systems (Cleveland), Inc.
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K081426
Trade/Device Name: NexStar Liftoff PET Application Software Suite
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: May 20, 2008
Received: May 21, 2008

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not Known

Device Name: NexStar Liftoff PET Application Software Suite

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Prescription Use ✓ **(Part 21 CFR 801 Subpart D)** **AND/OR** **Over-The-Counter Use** _____ **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081426