K140651
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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

JUN 11 2014

510(k) SUMMARY

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **Date Prepared:**
   March 12, 2014

6. **TRADE NAME(S):**
   Celesteion, PCA-9000A/2

7. **COMMON NAME:**
   System, X-ray, Computed Tomography
   System, Positron Emission Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR §892.1750 and 21 CFR §892.1200)

9. **PRODUCT CODE / DESCRIPTION:**
   JAK – System, Computed Tomography
   KPS – System, Positron Emission Tomography

10. **PERFORMANCE STANDARD:**
    This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

11. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Aquilion LB Triton, V4.91	Toshiba America Medical Systems	K123500	May 2, 2013
Gemini Raptor	Philips Healthcare	K052640	October 7, 2005

12. REASON FOR SUBMISSION:

New device

13. DEVICE DESCRIPTION:

Celesteion, PCA-9000A, is a large bore, TOF, PET-CT system, which combines a high-end CT system with a high-throughput PET system. The high-end CT system is a multi-slice helical CT scanner with a gantry aperture of 900 mm and a maximum scanning field of 700 mm. The high-throughput PET system has a time of flight (TOF) detector with temporal resolution of 450 ps. **Celesteion, PCA-9000A,** is intended to acquire PET images of any desired region of the whole body and CT images of the same region (to be used for attenuation correction or image fusion), to detect the location of positron emitting radiopharmaceuticals in the body with the obtained images. This device is used to gather the metabolic and functional information from the distribution of radiopharmaceuticals in the body for the assessment of metabolic and physiologic functions. This information can assist research, diagnosis, therapeutic planning, and therapeutic outcome assessment. This device can also function independently as a whole body multi-slice CT scanner.

14. INDICATIONS FOR USE:

The device is a diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT component produces cross- sectional images of the body by computer reconstruction of x-ray transmission data. The PET component images the distribution of PET radiopharmaceuticals in the patient body. The PET component utilizes CT images for attenuation correction and anatomical reference in the fused PET and CT images.

This device is to be used by a trained health care professional to gather metabolic and functional information from the distribution of the radiopharmaceutical in the body for the assessment of metabolic and physiologic functions. This information can assist in the evaluation, detection, diagnosis, therapeutic planning and therapeutic outcome assessment of (but not limited to) cancer, cardiovascular disease and brain dysfunction. Additionally, this device can be operated independently as a whole body multi-slice CT scanner.

15. SUBSTANTIAL EQUIVALENCE:

Celesteion, PCA-9000A/2, is substantially equivalent to the Gemini Raptor which was cleared via Pre-Market Notification 510(k), K052640, marketed by Philips Healthcare as Gemini TF Big Bore.

The CT portion of the **Celesteion, PCA-9000A/2**, is substantially equivalent to the Aquilion LB Triton system which received 510(k) clearance on May 2, 2013, per K123500. Some minor differences include the use of a moving table base and longer couch top in order to allow scanning in both CT and PET portions and the use of two consoles, one for scanning and one for display, instead of one console that performs both functions. The imaging chain including but not limited to the X-ray tube, detector and data acquisition system of the CT portion is identical to that of the Aquilion LB Triton.

The PET portions of the Celesteion and the Gemini Raptor operate on the same principles and basic technologies. Both systems acquire PET images and use their respective CT portions for attenuation correction. Additionally, both systems can combine PET and CT images as fused PET/CT images. The main difference between the systems is that the Celesteion requires a longer imaging duration (user selectable) to obtain equivalent data and image quality as compared to the predicate device.

A complete comparison table is included in this submission. See below for a brief comparison of the technological characteristics between the subject and the predicate devices:

Item	Celesteion PCA-9000A/2	Gemini Raptor	Aquilion LB Triton, V4.91
510(k) Number	This submission	K052640	K123500
PET Specifications			
Sensitivity (cps/kBq)	≥3.6	6.6	N/A
Count rate maximum NECR	61±10 kcps	90	N/A
System energy resolution	≤ 13.7%	11.7%	N/A
System timing resolution	≤ 450 ps	495 ps	N/A
Scatter fraction (%)	≤ 42.7	26	N/A
Spatial Resolution FWHM at 1cm	≤ 5.1	4.7	N/A
Performance Specifications			
Scan Regions	Whole body	Whole body	Whole body
CT scan FOV	70 cm	60 cm	70 cm
Scan System	CT: 360° continuous rotate/rotate	CT: 360° continuous rotate/rotate	CT: 360° continuous rotate/rotate
CT Specifications			
CT Detection System	16 row Solid State Detector	16 row Solid State Detector	16 row Solid State Detector
Output capacity	72 kW (max)	60 kW	72 kW (max)
X-ray Tube Voltage	80, 100, 120 and 135 kV	90, 120, 140 kVp	80, 100, 120 and 135 kV
X-ray Tube Current	10 mA to 600 mA	20-500 mA	10 mA to 600 mA
X-ray Tube Heat Capacity	7.5 MHU	8 MHU (Anode storage capacity)	7.5 MHU
X-ray Tube cooling rate	1,386 kHU/min (max) 1,008kHU/min (actual)	1,608 kHU/min (max)	1,386 kHU/min (max) 1,008kHU/min (actual)
Focal Spot Size (IEC)	0.09mm x 0.8mm (small) 1.6mm x 1.4 mm (large)	0.5mm x 1.0mm (small) 1.0mm x 1.0mm (large)	0.09mm x 0.8mm (small) 1.6mm x 1.4 mm (large)
Lowest couch height	475 mm (includes moving base)	Not available	312 mm (312 mm)
Couch-top stroke	2390 mm	Not available	2190 mm (1890 mm)

16. **SAFETY:**

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, IEC61223, NEMA PS 3.1-3.18, NEMA XR-25, NEMA XR-26 and NEMA NU2.

Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

17. TESTING

Risk analysis and verification/validation testing conducted through bench testing are included in this submission which demonstrates that the established specifications for the device have been met. CT image quality metrics were performed, utilizing phantoms, which validated that the subject device is substantially equivalent to the predicate device with regard to spatial resolution, CT number and contrast-to-noise ratio and noise properties. Additionally, PET image quality metrics were performed which validated that the subject device met established specifications for spatial resolution, sensitivity, NECR, energy/timing resolution and PET/CT alignment.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of the system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

18. CONCLUSION

Celesteion, PCA-9000A/2, performs in a manner that is similar to and is intended for the same use as the predicate devices, as indicated in product labeling. Based upon this information, conformance to standards, successful completion of software validation, application of risk management and design controls and the performance data presented in this submission it is concluded that the subject device is substantially equivalent in safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 11, 2014

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K140651
Trade/Device Name: Celesteion, PCA-9000A/2
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: March 12, 2014
Received: March 13, 2014

Dear Mr. Biggins:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140651

Device Name

Celesteion, PCA-9000A/2

Indications for Use *(Describe)*

The device is a diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT component produces cross-sectional images of the body by computer reconstruction of x-ray transmission data. The PET component images the distribution of PET radiopharmaceuticals in the patient body. The PET component utilizes CT images for attenuation correction and anatomical reference in the fused PET and CT images.

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Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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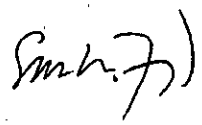
FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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