November 28, 2022

Voximetry, Incorporated
% Lisa Pritchard
VP, Regulatory, Quality, Clinical & Engineering
DuVal & Associates, P.A.
825 Nicollet Mall
Medical Arts Building # 1820
MINNEAPOLIS, MN 55402

Re: K220630
Trade/Device Name: Torch™ Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 3, 2022
Received: March 4, 2022

Dear Lisa Pritchard:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220630

Device Name
Torch™ Software

Indications for Use *(Describe)*
Torch™ software is intended to provide estimates (deterministic) of absorbed radiation dose at the voxel level following internal administration of approved radioactive products. This is dependent on input data regarding biodistribution being supplied to the application. Torch software only allows voxel-based dose calculations. For use with internally administered radioactive products. Torch should not be used to deviate from approved product dosing and administration instructions. Refer to the product's prescribing information for instructions.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Voximetry, Inc.
8517 Excelsior Drive, Suite 207
Madison, WI 53717

Phone: 262.751.6441
Email:swallace@voximetry.com

Contact Person: Sue Wallace, PhD
Date Prepared: November 25, 2022

II. DEVICE

Name of Device: Torch™ Software
Common or Usual Name: Torch
Classification Name: Radiological Image Processing System
Regulatory Class: II (21 C.F.R. 892.2050)
Product Code: LLZ

III. PREDICATE DEVICE

Primary:
Voxel Dosimetry V1.0, K191216
This predicate has not been subject to a design-related recall.

Additional:
OLINDA/EXM 2.0, K163687
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Torch is a software device for use in absorbed dose estimation of FDA approved radiopharmaceuticals. After administration of FDA approved radiopharmaceuticals, Torch provides post-treatment dosimetry evaluation on the voxel level using Monte Carlo techniques to assist the clinician in assessing absorbed dose to normal tissues and tumors.

Key functions of the Torch software include image import, image registration, contour propagation, pharmacokinetic modelling, and radiation transport modelling which is accelerated using parallel processing capabilities of Graphics Processing Units (GPUs). A Monte Carlo (MC) radiation transport algorithm is used to calculate absorbed dose with very high dosimetric accuracy.

Torch relies on medical images (e.g., positron emission tomography (PET), single photon emission computed tomography (SPECT), or computed tomography (CT)) which consist of a three-dimensional matrix of pixels, called voxels. Medical imaging acquired on the voxel level affords measurement of tissue heterogeneity and nonuniform source distribution of radiopharmaceuticals. Monte Carlo produces dose distributions at the voxel level with high precision.

V. INDICATIONS FOR USE

Torch™ software is intended to provide estimates (deterministic) of absorbed radiation dose at the voxel level following internal administration of approved radioactive products. This is dependent on input data regarding biodistribution being supplied to the application. Torch software only allows voxel-based dose calculations. For use with internally administered radioactive products. Torch should not be used to deviate from approved product dosing and administration instructions. Refer to the product's prescribing information for instructions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are designed for use by physicians to estimate delivered dosing of radiopharmaceutical therapy at the voxel level. Both are software devices that receive inputs from radiological images to estimate absorbed dose using the well-established Monte Carlo method. At a high level, the subject and predicate devices are based on the following same technological characteristics:

- Radiological Image Processing System – used to determine a delivered radiopharmaceutical dose at the voxel level;
- Software device for prescription use in a professional environment (e.g., clinic, hospital);
- No patient contact;
- Parses SPECT/CT or PET/CT DICOM data;
- Provides image registration of different time points to a common reference study;
- Generates and integrates voxel-level time-activity curves;
- Conducts voxel-level absorbed dose calculations using a Monte Carlo method;

- Provides absorbed dose map in DICOM format;
- Allows creation, transformation, and modification of contours/regions of interest to define objects in medical image volumes to support treatment calculation and evaluation;
- Supports computed tomography (CT), positron emission tomography (PET), and single photon emission computed tomography (SPECT); and
- Compatible radionuclide emissions include alphas, betas, and photons.

The following technological differences exist between the subject and predicate devices:

- Calculation method for Beta particle emissions (Torch uses full Monte Carlo method, primary predicate uses local energy deposition); and
- Torch only supports therapeutic radionuclides and does not support gamma emitting radionuclides which are used for imaging.

These minor differences in technological characteristics were determined to not raise any different questions of safety or effectiveness.

VII. PERFORMANCE DATA

Tests for verification and validation have been completed following Voximetry's design-control procedures. A risk analysis was completed, and risk controls implemented to mitigate identified hazards. Test results indicate that all specifications have met the acceptance criteria. As part of Verification, for each supported radionuclide (^{90}Y, ^{177}Lu, and ^{131}I), Torch absorbed dose was computed in tumors and critical organs in the ICRP 110 Adult Male reference dataset and compared with the average results from three established Monte Carlo codes: EGS++ 2018, GATE 8.1, and GEANT4 10.5 (i.e. the OpenDose project). All results indicated agreement within 5%. Details are shown in the table below.

Source Organ	**Difference [%] = 100% * (Torch-OpenDose)/OpenDose**		
	^{131}I	**^{90}Y**	**^{177}Lu**
Liver	-0.4	0.4	-0.7
Spleen	-1.3	0.3	-0.6
Right Kidney	-0.9	0.5	3.3
Left Kidney	-1.3	0.5	-0.6
Lumbar Spongiosa	-4.5	-4.2	-4.4
Left Lung	-0.8	1.8	2.1

Using the same phantom, additional testing was performed to validate the dose engine by computing total absorbed dose as well as separate dose contributions for each decay particle (alpha, beta, and gamma) and comparing to both OpenDose and the predicate device, OLINDA version 2.0.

Total absorbed dose agreed with both references within 5%, and individual contributions agreed within 5.2%. Details are shown in the table below.

Radionuclide	Statistic	Difference = 100% * (Torch-Reference)/Reference	
		OpenDose	OLINDA
Lu-177	Min	-5.21	-0.75
	Max	3.27	3.39
	Range	-5.21 – 3.27	-0.75 – 3.39
	Average	-0.23	0.44
I-131	Min	-5.59	-2.78
	Max	0.81	3.15
	Range	-5.59 – 0.81	-2.78 – 3.15
	Average	-1.12	-0.21
Y-90	Min	-4.22	-5.15
	Max	1.79	0.04
	Range	-4.22 – 1.79	-5.15 – 0.04
	Average	-0.09	-1.97

Again, using the same phantom, additional testing was performed to validate the dose engine by computing absorbed dose on a per-particle level for different source-target combinations, and comparing to OpenDose. Most results agreed with OpenDose computations within 1%, and all agreed within 5%.

Finally, Torch's Monte Carlo dose engine was tested against an established Monte Carlo dose algorithm (EGS) and physical film measurements, using 90Y and a custom-made puck-shaped film phantom developed in collaboration with the University of Wisconsin Accredited Dosimetry Calibration Laboratory. Torch agreed with measurements and previous calculations within 5%, as shown below.

Depth (mm)	Difference = 100% * (Torch-Reference)/Reference	
	Film Measurement	EGS
0	-1.67	1.82
0.9446	2.52	2.32
1.8892	4.25	2.23
2.8338	2.67	2.85
3.7784	2.54	1.60

No clinical studies were required for validation of the Torch software.

The testing results support that all the software specifications have met the acceptance criteria.

VIII. Substantial Equivalence

Torch™ operates on a voxel level and performs dose calculation for photons and electrons based on patient specific CT scans using full-Monte Carlo (FMC) method while Voxel Dosimetry uses the semi-Monte Carlo method (SMC). Torch refers to the same patient population as Voxel Dosimetry, supports the same isotopes (Lu-177, I-131, Y-90) and has equivalent intended use.

OLINDA/EXM® v2.0 is based on the use of S-factors, which are calculated on patient-like phantoms using a Monte Carlo method. The S-factors are equal to the average absorbed dose to a target organ generated by a unit of activity in a source organ. OLINDA/EXM® v2.0 dose calculations can thus be performed by multiplying the source organ time-activity curve integral by the S-factor. The FMC method used in Torch™, on the other hand, operates on a voxel level and performs dose calculations for photons and electrons based on patient specific CT scans. Therefore, Torch™ is patient-specific and produces voxel-level dose-maps instead of average organ-level dose estimates as OLINDA/EXM® v2.0 provides. Voxel Dosimetry ™ can also perform accurate lesion dosimetry because doses are calculated on a voxel-level and the same method can be used for lesions as for organs. This is not possible with OLINDA/EXM® v2.0, with which only a rough estimate of lesion doses is possible. Torch refers to the same patient population as OLINDA/EXM® v2.0.

IX. CONCLUSIONS

In summary, Torch™ v1.0, has the same Intended Use and similar technological characteristics that do not raise different questions of safety or effectiveness compared to the predicate devices. Therefore, Torch™ v1.0 is substantially equivalent to a combination of the predicate devices Voxel Dosimetry™ v1.0 (K191216) and OLINDA/EXM® v2.0 (K163687) and supports its clinical effectiveness, safety and intended use.