



December 5, 2024

AIQ Global, Inc.
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street
Floor 23
Philadelphia, Pennsylvania 19103

Re: K233998
Trade/Device Name: TRAQinform IQ
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ

Dear Kelliann Payne:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 5, 2024. Specifically, FDA is updating this SE Letter to address a typo in the IFU form as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Daniel Krainak, OHT8: Office of Radiological Health, 301-796-0478, daniel.krainak@fda.hhs.gov.

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: 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



September 5, 2024

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1735 Market Street
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Re: K233998
Trade/Device Name: TRAQinform IQ
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Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 18, 2023
Received: December 18, 2023

Dear Kelliann Payne:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: 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

Indications for Use

510(k) Number (if known)
K233998

Device Name

TRAQinform IQ

Indications for Use (Describe)

TRAQinform IQ is a software only device that provides a quantitative TRAQinform Report on lesions identified as Regions of Interest (ROI) in PET/CT DICOM compliant imaging data acquired, interpreted, and reported on per local practice prior to device use.

Clinicians responsible for patient care and for ordering TRAQinform Reports as an adjunct to locally reported image interpretation do not interact directly with the device. Clinicians responsible for local image interpretation do not interact with the device and generate their reporting before and independently of the TRAQinform Report.

The TRAQinform Report is generated by the device manufacturer and signed by a U.S. board certified physician responsible for supervising central report generation and qualified to practice nuclear radiology/medicine. The TRAQinform Report is for use by trained medical professionals including but not limited to oncologists, nuclear radiologists/physicians, medical imaging technologists, dosimetrists, and physicists.

TRAQinform IQ software contains the following functionalities:

- Automated matching of ROI between previously performed CT and PET/CT DICOM 3.0 volumetric medical images.
- In order to perform automated matching of ROI and quantitative analysis of previously performed CT and PET/CT DICOM 3.0 volumetric medical images, the software initially performs the following functions:
 - Machine learning skeletal and anatomic structure segmentation.
 - Threshold-based ROI identification and contouring.
- Automated quantitative analysis to assess previously performed CT and PET/CT DICOM 3.0 volumetric medical images, including: change in total volume and density of each identified ROI, and change in Fludeoxyglucose F18 (FDG) tracer uptake of each identified ROI among images.
- Generation of images of the anatomy combined with spatial and quantitative information, including computed classification of quantitative FDG ROI changes.

For multi-timepoint quantitative analysis, recommended use is in adult patients 22 years and older with partial or whole-body PET/CT acquired following administration of FDG per approved drug prescribing information and with the second FDG administration separated from the first by a period not to exceed 12 months.

For single-timepoint quantitative analysis, recommended use is in adult patients 22 years and older with partial or whole-body PET/CT following administration of FDG, a PSMA targeted PET drug, or a SSTR-targeted PET drug per approved drug prescribing information.

Discrepancies between TRAQinform IQ and local PET/CT reporting have been investigated and use of TRAQinform IQ has not been established for binary patient level progression or non-progression decisions without multidisciplinary review. Discrepancies between TRAQinform IQ and local PET/CT reporting that could impact patient care should therefore prompt consultation with subject matter experts (for example, in tumor board), with a patient-centered focus on discrepant imaging regions and with blinded or otherwise neutral adjudication regarding interpretation/classification source.

TRAQinform IQ is not intended to diagnose any disease, replace the diagnostic procedures for interpretation of CT or PET/CT images, recommend any specific treatment, nor is it intended to replace the skill and judgment of a qualified medical professional.

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.

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K233998

510(k) SUMMARY
AIQ Global, Inc's TRAQinform IQ

Submitter

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Contact Person

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Date Prepared

August 28, 2024

Device Identification

Proprietary Name: TRAQinform IQ
Common Name: System, Image Processing, Radiological
Regulation No: 21 CFR 892.2050 *Picture Archiving and Communications System*
Product Code: LLZ
Regulatory Class: Class II
Classification Panel: Radiology

Predicate Device

Name of Device: QTxl
510(k) Number: K173444
Regulation No: 21 CFR 892.2050
Product Code: LLZ
Regulatory Class: Class II
Classification Panel: Radiology

Reference Device

Name of Device: MIM 4.1 (SEASTAR)
510(k) Number: K071964
Regulation No: 21 CFR 892.2050
Product Code: LLZ
Regulatory Class: Class II
Classification Panel: Radiology

Device Description and Technological Characteristics

TRAQinform IQ is a software only device that provides quantitative analysis of lesions identified as Regions of Interest (ROI) in PET/CT DICOM compliant imaging data acquired, interpreted, and reported on per local practice prior to device use.

The input to TRAQinform IQ is CT and PET/CT images as supported by ACR/NEMA DICOM 3.0.

The following steps are performed by the software:

- Automatic threshold-based ROI segmentation:
 - ROI can also be imported from external sources (other validated tools or manual contouring by qualified medical personnel).
- Automatic ROI registration between multiple images:
 - Images can be from the same or different imaging modality.
 - Images can be from the same or different PET tracer.
 - Images can be from the same or different date.
- Automatic matching of ROI between multiple, previously performed images.
- Automatic quantification of dynamic changes among images including, but not limited to:
 - Changes in ROI shape.
 - Single ROI splitting into multiple ROI.
 - Multiple ROI combining into a single ROI.
 - ROI appearing, disappearing, and re-appearing across images.
- A comprehensive summary analysis.

TRAQinform IQ calculates spatial and quantitative metrics for each individual ROI. These metrics are provided as a TRAQinform Report. TRAQinform IQ uses computational algorithms to detect, fuse and analyze ROI and provides the following outputs:

- Identification of anatomic location of ROI in all areas of the body.
- A quantitative analysis of functional and anatomic data for CT and PET/CT scans, including:
 - Volume of all identified ROI on each image;
 - Change in volume of each identified ROI among images;
 - Total volume of all identified ROI on each image;
 - Change in total volume of all identified ROI on each image;
 - Heterogeneity of change in volume of each identified ROI;
 - For PET scans:
 - Tracer uptake (SUVmax, SUVtotal, SUVmean, SUVhetero) of each identified ROI on each image;
 - Change in tracer uptake (SUVmax, SUVtotal, SUVmean) of each identified ROI among images;
 - Total tracer uptake (SUVmax, SUVtotal, SUVmean, SUVhetero) of all identified ROI on each image;
 - Change in total tracer uptake (SUVmax, SUVtotal, SUVmean, SUVhetero) of all identified ROI on each image;
 - Heterogeneity of change in tracer uptake (SUVhetero) among identified ROI.
 - For CT scans
 - Radio density (HUmax, HUtotal, HUmean, HUhetero) for each identified ROI on each

- image;
 - Changes in radio density (HUmax, HUtotal, HUmean) of all identified ROI on each image;
 - Change in total radio density (HUmax, HUtotal, HUmean, HUhetero) of all identified ROI on each image;
 - Heterogeneity of change in radio density (HUhetero) among identified ROI.
- 2D graphical renderings of medical images, including Maximum Intensity Projections of the PET and CT, with overlaid and labeled/color-coded ROI, for inclusion in TRAQinform Reports.
- 3D labeled contours for ROI, anatomic structures, and skeletal structures.

The TRAQinform IQ software operates in a secure cloud environment.

Intended Use / Indications for Use

TRAQinform IQ is a software only device that provides a quantitative TRAQinform Report on lesions identified as Regions of Interest (ROI) in PET/CT DICOM compliant imaging data acquired, interpreted, and reported on per local practice prior to device use.

Clinicians responsible for patient care and for ordering TRAQinform Reports as an adjunct to locally reported image interpretation do not interact directly with the device. Clinicians responsible for local image interpretation do not interact with the device and generate their reporting before and independently of the TRAQinform Report.

The TRAQinform Report is generated by the device manufacturer and signed by a U.S. board certified physician responsible for supervising central report generation and qualified to practice nuclear radiology/medicine. The TRAQinform Report is for use by trained medical professionals including but not limited to oncologists, nuclear radiologists/physicians, medical imaging technologists, dosimetrists, and physicists.

TRAQinform IQ software contains the following functionalities:

- Automated matching of ROI between previously performed CT and PET/CT DICOM 3.0 volumetric medical images.
- In order to perform automated matching of ROI and quantitative analysis of previously performed CT and PET/CT DICOM 3.0 volumetric medical images, the software initially performs the following functions:
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Discrepancies between TRAQinform IQ and local PET/CT reporting have been investigated and use of TRAQinform IQ has not been established for binary patient level progression or non-progression decisions without multidisciplinary review. Discrepancies between TRAQinform IQ and local PET/CT reporting that could impact patient care should therefore prompt consultation with subject matter experts (for example, in tumor board), with a patient-centered focus on discrepant imaging regions and with blinded or otherwise neutral adjudication regarding interpretation/classification source.

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Performance Testing

Results of software validation and verification (V&V) and early feasibility testing of device component functionality for CT segmentation, regional PET thresholding, and ROI matching supported further FDG test-retest and pivotal device output investigation. For detail on component testing, published reporting is available respectively in Weisman 2023 (CT anatomy segmentation, doi.org/10.1088/2057-1976/acfb06), Perk 2018 (ROI detection methodology, doi.org/10.1088/1361-6560/aaebba), and Huff 2023 (ROI matching, doi.org/10.1088/1361-6560/acef8f).

Test-Retest

This study established test-retest limits of agreement used to categorize regions of interest based off changes between FDG PET/CT images. 31 patients with non-small lung cancer patients received two FDG PET/CT images within 1 week pretreatment. The limits of repeatability endpoint estimated the interval within which 95% of repeated measurements are expected to lie when clinically relevant change is lacking. For TRAQinform IQ generated features, these limits are shown in **Table 1**.

Table 1: Lower and upper limits of repeatability for each imaging feature.

Feature	Lower limit (%)	Upper limit (%)
SUVmax	-27.0	56.8
SUVmean	-20.2	38.5
SUVtotal	-54.1	144.5
Volume	-52.6	113.9

Pivotal Reader Study

A study was conducted to evaluate the clinical utility of TRAQinform IQ. In this study, three report evaluators (oncologists) were assigned to distinguish each of 103 patients as positive versus

negative for progression based on presentation of the locally generated radiology report without and then with adjunctive presentation of the TRAQinform Report.

Each of the 103 patients had two sequential FDG PET/CT scans acquired between 2005 and 2022. Scans were acquired from patients scanned at 10 or more imaging centers in at least 3 U.S. states (exact image center information was redacted on scan transfer). A full breakdown is shown in **Table 2**. A breakdown of patients by disease type, patient sex, weight, and age are also shown in **Table 2**. Out of the 206 total scans (2 per patient), scanner information was available for 199 (99 patients). Scans were acquired on a variety of scanner manufacturers and models, with 84 patients receiving scans on the same scanner for baseline and follow-up.

A total of 1046 ROI were detected across the baseline scans (median per patient: 6, range: 0-80) and 935 were detected on the follow-up (median per patient: 4, range: 0-60).

Table 2: Patient and scan characteristics for all patients and scans where information was not redacted during the scan transfer process.

Imaging Site / Location	Site 1 (North Carolina, USA), <i>n</i> = 35 Site 2 (Unknown State, USA), <i>n</i> = 31 Site 3 (North Carolina, USA), <i>n</i> = 13 Site 4 (North Carolina, USA), <i>n</i> = 12 Site 5 (Iowa, USA), <i>n</i> = 4 Site 6 (North Carolina, USA), <i>n</i> = 3 Site 7 (North Carolina, USA), <i>n</i> = 2 Site 8 (Unknown State, USA), <i>n</i> = 1 Site 9 (North Carolina, USA), <i>n</i> = 1 Site 10 (Missouri, USA), <i>n</i> = 1
Cancer Type, n	Breast Cancer, <i>n</i> = 23 Lung Cancer, <i>n</i> = 20 Prostate, <i>n</i> = 16 Melanoma, <i>n</i> = 15 Head & Neck Cancer, <i>n</i> = 8 Lymphoma, <i>n</i> = 7 Colorectal Cancer, <i>n</i> = 6 Other, <i>n</i> = 5 Gynecological Cancer, <i>n</i> = 3
Patient sex, n <i>Female / Male</i>	57/46
Patient age, years <i>Median (range)</i>	66 (26, 87)
Patient weight, kg <i>Median (range)</i>	78.5 (43.0, 132.9)
Patient Race	Unreported, <i>n</i> = 75 White, <i>n</i> = 25 Hispanic, <i>n</i> = 2 Black, <i>n</i> = 1

Scanner model <i>(n=199)</i>	Siemens Healthineers Biograph 20, <i>n = 76</i> Siemens Healthineers BioGraph TruePoint, <i>n = 46</i> Canon Medical Systems Celesteion, <i>n = 41</i> Canon Medical Systems Cartesion Prime, <i>n = 14</i> GE Healthcare Discovery ST, <i>n = 12</i> Siemens Healthineers Biograph6, <i>n = 7</i> Siemens Healthineers Biograph Horizon, <i>n = 3</i>
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Of the 103 patients investigated, the TRAQInform Report prompted at least one oncologist interpreter to reevaluate 23 patients classified without the device as negative for progression to positive, and to reevaluate 9 patients classified without the device as positive for progression to negative. In these cases, the oncologist interpreter highlighted a subset of ROI for further review. Imaging and local reporting on these 23 + 9 = 32 patients was sent to a panel of two radiologists and one oncologist, together serving as a reference source against which to quantify positive percent agreement (PPA, representing patients classified as positive by both the panel and an oncologist), negative percent agreement (NPA; representing patients classified as negative by both the panel and an oncologist), and the 95% confidence interval (95%CI) for overall percent agreement (OPA; prevalence-biased PPA and NPA aggregation). Compared to chance performance (50%), the 95% CI for OPA was 41% to 76%. PPA was 14/18=78% and NPA was 5/14=36%.

Because reevaluation at the patient level was derived from reporting at a lower ROI level, panel agreement was also evaluated at this level. The panel examined only the subset of ROI that had been highlighted by the report evaluators. Of 111 total ROIs highlighted on the TRAQInform Report, the panel agreed with the device classification (new, increasing, unchanged, decreasing, and disappearing) in 37/53=70%, 18/26=70%, 11/13=85%, 5/8 (63%), and 10/11 (90%) ROIs, respectively.

Comparison of Technological Characteristics to Predicate

TRAQinform IQ is a modification of the predicate device. Both the subject and predicate devices are intended to be used by trained medical professionals as an aid in evaluation and information management of digital medical images. Specifically, both devices are radiological image processing systems intended to assess patient radiological scans to provide supplemental information to physicians on changes to regions of interest (ROI).

Comparison of key technological features are provided in **Table 3**.

Conclusion

The TRAQinform IQ has the same intended use and similar indications, technological characteristics, and principles of operation as the predicate device. Differences do not alter the intended use of the device and do not raise different questions of safety and effectiveness when used as labeled. The performance data demonstrate that the TRAQinform IQ is as safe and effective as the QTxl. Thus, the TRAQinform IQ is substantially equivalent.

Table 3: Substantial Equivalence Table

Specification / Characteristic	TRAQinform IQ <i>Subject Device</i>	Quantitative Total Extensible Imaging (QTxl) (K173444) <i>Predicate Device</i>
Product Code	LLZ	LLZ
Regulation Number	892.2050	892.2050
Regulatory Class	II	II
Review Panel	Radiology	Radiology
Users	Trained medical professionals including, but not limited to, radiologists, oncologists, nuclear medicine physicians, medical imaging technologists, dosimetrists and physicists.	Trained medical professionals including, but not limited to, radiologists, oncologists, nuclear medicine physicians, medical imaging technologists, dosimetrists and physicists.
Intended Use	A software tool to aid in evaluation and information management of digital medical images.	A software tool to aid in evaluation and information management of digital medical images.
Indications for Use	<p>TRAQinform IQ is a software only device that provides quantitative analysis of lesions identified as Regions of Interest (ROI) in PET/CT DICOM compliant imaging data acquired, interpreted, and reported on per local practice prior to device use.</p> <p>Clinicians responsible for patient care and for ordering TRAQinform Reports as an adjunct to locally reported image interpretation do not interact directly with the device. Clinicians responsible for local image interpretation do not interact with the device and generate their reporting before and independently of the TRAQinform Report.</p> <p>The TRAQinform Report is generated by the device manufacturer and signed by a U.S. board certified physician responsible for supervising central report generation and qualified to practice nuclear radiology/medicine. The TRAQinform Report is for use by trained medical professionals including but not limited to oncologists, nuclear radiologists/physicians, medical imaging technologists, dosimetrists, and physicists.</p>	<p>Quantitative Total Extensible Imaging (QTxl) is a software tool used to aid in evaluation and information management of digital medical images by trained medical professionals including, but not limited to, radiologists, oncologists, nuclear medicine physicians, medical imaging technologists, dosimetrists and physicists. The medical modalities of these medical images include, but are not limited to, DICOM CT and PET as supported by ACR/NEMA DICOM 3.0.</p>

Specification / Characteristic	TRAQinform IQ <i>Subject Device</i>	Quantitative Total Extensible Imaging (QTxl) (K173444) <i>Predicate Device</i>
	<p>TRAQinform IQ software contains the following functionalities:</p> <ul style="list-style-type: none"> • Automated matching of ROI between previously performed CT and PET/CT DICOM 3.0 volumetric medical images. • In order to perform automated matching of ROI and quantitative analysis of previously performed CT and PET/CT DICOM 3.0 volumetric medical images, the software initially performs the following functions: <ul style="list-style-type: none"> ▪ Machine learning skeletal and anatomic structure segmentation. ▪ Threshold-based ROI identification and contouring. • Automated quantitative analysis to assess previously performed CT and PET/CT DICOM 3.0 volumetric medical images, including: change in total volume and density of each identified ROI, and change in Fludeoxyglucose F18 (FDG) tracer uptake of each identified ROI among images. • Generation of images of the anatomy combined with spatial and quantitative information, including computed classification of quantitative FDG ROI changes. 	<p>QTxl assists in the following indications:</p> <ul style="list-style-type: none"> • Receive, store, retrieve, display and process digital medical images • Create, display and print reports from those images • Provide medical professionals with the ability to display, register, and fuse medical images • Identify Regions of Interest (ROIs) and perform ROI contouring allowing quantitative/statistical analysis of full or partial body scans • Evaluate quantitative change in ROIs (total or partial body; individual ROI within individual) with 3D interactive rendering of images with highlighted ROIs.

Specification / Characteristic	TRAQinform IQ <i>Subject Device</i>	Quantitative Total Extensible Imaging (QTxl) (K173444) <i>Predicate Device</i>
	<p>For multi-timepoint quantitative analysis, recommended use is in adult patients 22 years and older with partial or whole-body PET/CT acquired following administration of FDG per approved drug prescribing information and with the second FDG administration separated from the first by a period not to exceed 12 months.</p> <p>For single-timepoint quantitative analysis, recommended use is in adult patients 22 years and older with partial or whole-body PET/CT following administration of FDG, a PSMA targeted PET drug, or a SSTR-targeted PET drug per approved drug prescribing information.</p> <p>Discrepancies between TRAQinform IQ and local PET/CT reporting have been investigated and use of TRAQinform IQ has not been established for binary patient level progression or non-progression decisions without multidisciplinary review. Discrepancies between TRAQinform IQ and local PET/CT reporting that could impact patient care should therefore prompt consultation with subject matter experts (for example, in tumor board), with a patient-centered focus on discrepant imaging regions and with blinded or otherwise neutral adjudication regarding interpretation/classification source.</p> <p>TRAQinform IQ is not intended to diagnose any disease, replace the diagnostic procedures for interpretation of CT or PET/CT images, recommend any specific treatment, nor is it intended to replace the skill and judgement of a qualified medical professional.</p>	

Specification / Characteristic	TRAQinform IQ <i>Subject Device</i>	Quantitative Total Extensible Imaging (QTxl) (K173444) <i>Predicate Device</i>
Medical Modalities	CT and PET/CT images as supported by ACR/NEMA DICOM 3.0 Radiotracers for multiple timepoints: FDG Radiotracers for single timepoint: FDG, PSMA-targeted PET drug, or a SSTR-targeted PET drug	DICOM, CT, MRI, SPECT and PET as supported by ACR/NEMA DICOM 3.0 Radiotracers: NaF PET
Operating System	Secure Cloud Environment with Web Browser Interface	Windows 7 or Windows 10
Identification of ROI	Automatic Threshold based ROI identification in bone and anatomical structures	Threshold based ROI identification in bone
Importation of ROI contours	TRAQinform IQ allows the importation of physician established contours of ROI	No importation functionality
Segmentation	Segmentation of bone to identify skeletal structures and segmentation of anatomical structures to identify organs. Segmentation is driven by machine learning algorithms.	Atlas based segmentation of bone to identify skeletal structures
Quantitative Analysis	Scan-to-scan registration and ROI matching allows automatic quantification of ROIs and assessment of changes/differences in ROI: <ul style="list-style-type: none"> • Changes in ROI shape • Single ROI splitting into multiple ROI • Multiple ROI combining into a single ROI • ROI appearing, disappearing, and re- appearing across images Quantitative analysis of functional and anatomical data for CT and PET/CT scans, including: <ul style="list-style-type: none"> • Volume of each identified ROI on each image • Change in volume of each identified ROI among images • Total volume of all identified ROI on each image 	Scan-to-scan registration and ROI matching allows automatic quantification of ROIs and assessment of changes/differences in ROI. Quantitative/statistical analysis of full or partial-body scans

Specification / Characteristic	TRAQinform IQ Subject Device	Quantitative Total Extensible Imaging (QTxl) (K173444) Predicate Device
	<ul style="list-style-type: none"> • Change in total volume of all identified ROI on each image • Heterogeneity of change in volume of each identified ROI <p>For PET scans:</p> <ul style="list-style-type: none"> • Tracer uptake (SUVmax, SUVtotal, SUVmean, SUVhetero) of each identified ROI on each image • Change in tracer uptake (SUVmax, SUVtotal, SUVmean) of each identified ROI among images • Total tracer uptake (SUVmax, SUVtotal, SUVmean, SUVhetero) of all identified ROI on each image • Change in total tracer uptake (SUVmax, SUVtotal, SUVmean, SUVhetero) of all identified ROI on each image • Heterogeneity of change in tracer uptake (SUVhetero) among identified ROI <p>For CT scans:</p> <ul style="list-style-type: none"> • Radio density (HUmax, HUtotal, HUmean, HUhetero) for each identified ROI on each image • Changes in radio density (HUmax, HUtotal, HUmean) of all identified ROI on each image • Change in total radio density (HUmax, HUtotal, HUmean, HUhetero) of all identified ROI on each image • Heterogeneity of change in radio density (HUhetero) among identified ROI <p>2D Graphical renderings of medical images, including Maximum Intensity Projections of the PET and CT, with overlaid and labeled/color-coded ROI for inclusion in TRAQinform Reports.</p> <p>3D labeled contours for ROI, anatomic structures, and skeletal structures.</p>	