



August 13, 2024

Turing Medical Technologies, Inc.
Christa Nova
Lead Manager of QARA (Quality Assurance and Regulatory Affairs)
393 N Euclid Ave
Suite 310
Saint Louis, Missouri 63108

Re: K241094

Trade/Device Name: Bullsai
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 18, 2024
Received: July 18, 2024

Dear Christa Nova:

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.

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,



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

Submission Number (if known)

K241094

Device Name

Bullsai

Indications for Use (Describe)

Bullsai is composed of a set of modules intended for analysis and processing of medical images and other healthcare data. It includes functions for image manipulation, basic measurements, and planning.

Bullsai is indicated for use in image processing, registration, atlas-assisted visualization and segmentation, and target export creation and selection of structural MRI images, where an output can be generated for use by a system capable of reading DICOM image sets.

Bullsai is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white matter tracts based on diffusion reconstruction methods and for the use of said maps to select and create exports.

Typical users of Bullsai are medical professionals, including but not limited to surgeons, clinicians, and radiologists.

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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510(k) Summary

Device Trade Name: Bullsai

Manufacturer: Turing Medical Technologies, Inc.
393 N EUCLID AVE STE 310,
SAINT LOUIS, MISSOURI 63108 UNITED STATES

Contact: Christa Nova
Lead Manager of QARA
419-388-3288

Date Prepared: August 9, 2024

Classification: Medical image management and processing system, 21 CFR
892.2050

Class: II

Product Code: LLZ

Primary Predicate: Quicktome Software Suite, K222359

Indications For Use:

Bullsai is composed of a set of modules intended for analysis and processing of medical images and other healthcare data. It includes functions for image manipulation, basic measurements, and planning.

Bullsai is indicated for use in image processing, registration, atlas-assisted visualization and segmentation, and target export creation and selection of structural MRI images, where an output can be generated for use by a system capable of reading DICOM image sets.

Bullsai is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white matter tracts based on diffusion reconstruction methods and for the use of said maps to select and create exports.

Typical users of Bullsai are medical professionals, including but not limited to surgeons, clinicians, and radiologists.

Device Description:

Bullsai is a software-only, cloud-deployed, image processing package which can be used to perform DICOM image processing and analysis.

Bullsai can receive (“import”) DICOM images from picture archiving and communication systems (PACS), including Diffusion Weighted Imaging (DWI) and structural brain imaging.

Bullsai removes protected health information (PHI) and links the dataset to an encryption key, which is then used to relink the data back to the patient when the data is exported to a medical imaging platform such as a hospital PACS or other DICOM device.

The software provides a workflow for a clinician to:

- Select an image for planning and visualization,
- Validate image quality,
- Export black and white and color DICOMs for use in systems that can view DICOM images.

Bullsai uses advanced MRI processing to deliver patient-specific anatomy and tractography results to support physicians in neurosurgical planning. Bullsai preprocessing steps include denoising, debiasing, skull stripping, susceptibility distortion and head motion correction to ensure input data can support generation of tractography and segmentation results. Bullsai uses generalized q-sampling imaging (GQI) to estimate the voxel-level white matter microstructure: GQI is a model-free diffusion reconstruction method that uses the Fourier transform relationship between the diffuse MR signal and the potential diffusion displacement for resolving fiber orientations and the anisotropy of water. Patient-specific anatomical segmentation and GQI estimated fiber orientations are used in Bullsai as part of an iterative heuristic tractography algorithm that emulates the manual work of neuroanatomists who iteratively seed tracts and remove aberrant fibers. Results are shared as DICOM outputs which can readily be viewed and edited in standard neurosurgical planning software packages.

Predicate Device:

Turing Medical Technologies, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA’s regulation of medical devices, Bullsai is substantially equivalent in indications, design principles, and performance to the following predicate device, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: Quicktome Software Suite (K222359)

Performance Testing Summary:

Software verification and validation testing were conducted. Documentation and relevant standards were provided.

Substantial Equivalence:

Item	Predicate: Quicktome Software Suite K222359	Subject Device: Bullsai	Comparison
Classification	Class II	Class II	Identical
Product Code	LLZ	LLZ	Identical

Device Description	Quicktome is a software-only, cloud- deployed, image processing package which can be used to perform DICOM image viewing, image processing, and analysis. Quicktome can receive (“import”) DICOM images from picture archiving and communication systems (PACS), acquired with MRI, including Diffusion Weighted Imaging (DWI) sequences, T1, T2, BOLD, and FLAIR images. Quicktome can also receive Resting State functional MRI (rs-fMRI) blood- oxygen-level-dependent (BOLD) datasets. Once received, Quicktome removes protected health information (PHI) and links the dataset to an encryption key, which is then used to relink the data back to the patient when the data is exported to hospital PACS or other DICOM device. The software provides a workflow for a clinician to: • Select an image for planning and visualization, • Validate image quality, • Explore the available anatomical regions, network templates, tractography bundles, and parcellations, • Select regions of interest, • Display resting state fMRI (BOLD) correlation maps using task-analogous seeds for Motor, Vision and Language networks, and • Export black and white and color DICOMs for use in systems that can view DICOM images.	Bullsai is a software-only, cloud-deployed, image processing package which can be used to perform DICOM image processing and analysis. Bullsai can receive (“import”) DICOM images from picture archiving and communication systems (PACS), including Diffusion Weighted Imaging (DWI) and structural brain imaging. Bullsai removes protected health information (PHI) and links the dataset to an encryption key, which is then used to relink the data back to the patient when the data is exported to a medical imaging platform such as a hospital PACS or other DICOM device. The software provides a workflow for a clinician to: • Select an image for planning and visualization, • Validate image quality, • Export black and white and color DICOMs for use in systems that can view DICOM images. Bullsai uses advanced MRI processing to deliver patient-specific anatomy and tractography results to support physicians in neurosurgical planning. Bullsai preprocessing steps include denoising, debiasing, skull stripping, susceptibility distortion and head motion correction to ensure input data can support generation of tractography and segmentation results. Bullsai uses generalized q-sampling imaging (GQI) to estimate the voxel-level white matter microstructure: GQI is a model-free diffusion reconstruction method that uses the Fourier transform relationship between the diffuse MR signal and the potential diffusion displacement for resolving fiber orientations and the anisotropy of water. Patient-specific anatomical segmentation and GQI estimated fiber orientations are used in Bullsai as part of an iterative heuristic tractography algorithm that emulates the manual work of neuroanatomists who iteratively seed tracts and remove aberrant fibers. Results are shared as DICOM outputs which can readily be viewed and edited in standard neurosurgical planning software packages.	Similar; 1) Bullsai does not have a viewer and therefore does not provide display, image viewing, or clinician exploration of device outputs within the device. 2) Bullsai does not support the processing or visualization of resting-state MRI studies. 3) Description of the process and GQI included.
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Item	Predicate: Quicktome Software Suite K222359	Subject Device: Bullsai	Comparison
Indication for Use	The Quicktome Software Suite is composed of a set of modules intended for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, planning, 3D visualization (MPR reconstructions and 3D volume rendering) and display of BOLD (blood oxygen level dependent) resting-state MRI scan studies. Modules are available for image processing, atlas-assisted visualization and segmentation, resting state analysis and visualization, and target export creation and selection, where an output can be generated for use by a system capable of reading DICOM image sets. Quicktome is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white matter tracts based on constrained spherical deconvolution methods and for the use of said maps to select and create exports. Quicktome can generate motor, language, and vision resting state fMRI correlation maps using task-analogous seeds. Typical users of Quicktome are medical professionals, including but not limited to surgeons, clinicians, and radiologists.	Bullsai is composed of a set of modules intended for analysis and processing of medical images and other healthcare data. It includes functions for image manipulation, basic measurements, and planning. Bullsai is indicated for use in image processing, registration, atlas-assisted visualization and segmentation, and target export creation and selection of structural MRI images, where an output can be generated for use by a system capable of reading DICOM image sets. Bullsai is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white matter tracts based on diffusion reconstruction methods and for the use of said maps to select and create exports. Typical users of Bullsai are medical professionals, including but not limited to surgeons, clinicians, and radiologists.	Similar; 1) Bullsai does not have a viewer and therefore does not provide display, image viewing, or 3D visualization. 2) Bullsai does not support the processing or visualization of resting-state MRI studies. 3) Bullsai uses diffusion reconstruction methods rather than constrained spherical deconvolution methods.

Bullsai is substantially equivalent to the identified predicate (legally marketed) device. Bullsai has the same intended use and technological characteristics as the predicate device and or different intended use and technological characteristics that do not raise different questions of safety and effectiveness.

At a high level, Bullsai and predicate device are based on the following same elements:

- Bullsai is composed of a set of modules intended for medical images and other healthcare data.
- Bullsai includes functions for image manipulation, basic measurements, and planning.
- Bullsai modules are available for image processing, atlas-assisted visualization and segmentation, and target export creation and selection, where an output can be generated for use by a system capable of reading DICOM image sets.
- Bullsai is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white matter tracts and for the use of said maps to select and create exports.
- Typical users of Bullsai are medical professionals, including but not limited to surgeons, clinicians, and radiologists.
- Bullsai is a software-only, cloud-deployed, image processing package which can be used

to perform DICOM image processing and analysis.

- Bullsai can receive (“import”) DICOM images from picture archiving and communication systems (PACS).
- Bullsai provides support to structural imaging techniques including Diffusion Weighted Imaging (DWI).
- Bullsai accepts standardized imaging formats for volumetric medical imaging.
- Bullsai removes protected health information (PHI) and links the dataset to an encryption key, which is then used to relink the data back to the patient when the data is exported to a medical imaging platform such as a hospital PACS or other DICOM device.
- Bullsai provides a workflow for a clinician to select an image for planning and visualization, validate image quality, and export black and white and color DICOMs for use in systems that can view DICOM images.

At a high level, Bullsai and predicate device have the following different elements:

- Bullsai does not have a viewer and therefore does not provide display, image viewing, 3D visualization, or clinician exploration of device outputs within the device.
- Bullsai does not support the processing or visualization of resting-state MRI studies.
- Bullsai uses diffusion reconstruction methods rather than constrained spherical deconvolution methodologies, to process diffusion-weighted MRI sequences into 3D maps that represent white matter tracts. Generalized q-sampling imaging (GQI) is a model-free diffusion reconstruction method that uses the Fourier transform relationship between the diffuse MR signal and the potential diffusion displacement for resolving fiber orientations and the anisotropy of water.

Validation of differences compared to predicate devices:

- Clinical accuracy of the Bullsai device outputs were evaluated and validated by clinical experts for the clinical intended uses of presurgical planning.
- Bullsai device output’s were validated compatibility with major neuronavigation software systems.
- Bullsai device output’s were validated for repeatability and reproducibility across major scanner manufacturer brands.

Differences:

- The predicate device conducted a summative usability evaluation and design validation with representative users; Bullsai does have a viewer and therefore a usability study was not conducted.
- The predicate device conducted performance evaluations for their BOLD processing pipeline. Bullsai does not support resting-state BOLD MRI data and therefore a similar study was not conducted.
- The predicate device compared resting state fMRI correlation maps to task-based fMRI activation maps; Bullsai does not support resting state fMRI data and therefore a similar study was not conducted.

Conclusion:

The subject device and the predicate devices have the same intended use and have similar technological characteristics. The data included in this submission demonstrate substantial equivalence to the predicate device listed above. Bullsai is as safe, as effective, and performs as well as, or better, than the predicate device.