February 19, 2025

Brainomix Limited
% Zsolt Szrnka
Regulatory Affairs Manager
First Floor, Seacourt Tower
West Way
OXFORD, OX2 0JJ
UNITED KINGDOM

Re: K242411
Trade/Device Name: Brainomix 360 e-Lung
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: August 14, 2024
Received: January 16, 2025

Dear Zsolt Szrnka:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242411

Device Name

Brainomix 360 e-Lung

Indications for Use *(Describe)*

The e-Lung software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support in the examination of radiological findings. These radiological findings can then be evaluated by the physician in conjunction with a range of ancillary information to form a potential diagnosis or list of likely diagnoses. The e-Lung software package is intended to be a workflow enhancement and visualization tool for the assessment of CT thoracic datasets. e-Lung can be used to support the physician when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets. 3D segmentation, volumetric measurements, density evaluations, and reporting tools are combined with a dedicated workflow.

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.

Head office
First Floor, Seacourt Tower, West Way
Oxford OX2 0JJ, United Kingdom

510(k) Summary
Brainomix Limited – Brainomix 360 e-Lung

Date Prepared:	16Jan2025
Applicant's Name:	Brainomix Limited
Applicant's Address:	First Floor, Seacourt Tower, West Way Oxford, OX 0JJ United Kingdom
Official Contact:	Zsolt Szrnka +44 (0) 1865 582730 regulatory@brainomix.com
Device Proprietary Name:	Brainomix 360 e-Lung
Device Classification Name:	System, X-Ray, Tomography, Computed
Regulatory Class:	Class II
Product Code:	JAK
Regulation Number:	21 C.F.R. §892.1750
Regulation Name:	Computed tomography x-ray system

1. Predicate Device

Brainomix 360 e-Lung is Substantially Equivalent to the following Legally Marketed device:

Trade Name: Brainomix 360 e-Lung
Manufacturer: Brainomix Ltd.
Regulation Number: 21 C.F.R. §892.1750
Regulatory Class: Class II
Regulation Name: Computed tomography x-ray system
Product Code: JAK
Submission Number: K233875

2. Device Description

Brainomix 360 e-Lung is a software package compliant with the DICOM standard and running on an off-the-shelf physical or virtual server. e-Lung is a CT processing module which operates within the integrated Brainomix 360 platform.

Brainomix 360 e-Lung is a stand-alone software device which uses a set of image processing algorithms to perform evaluation (3D segmentation and isolation of sub-compartments, volumetric measurements, and density evaluations), editing, and reporting tools which are combined with a dedicated workflow.

e-Lung can be used to support the physician in the documentation of radiological findings that may be indicative of chest diseases when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets. These radiological findings are then evaluated in conjunction with a range of ancillary information to form a potential diagnosis or list of likely diagnoses.

e-Lung is designed to analyze pulmonary CT slice data and display analysis results. Each voxel of the scan is measured by Hounsfield units (HU), a measurement of x-ray attenuation that is applied to each volume element in three-dimensional space. The HU are utilized to distinguish between air, water, tissue and bone, such distinction is common in the industry.

e-Lung provides computed tomography (CT) viewing, and parenchymal density analysis in one application. e-Lung provides quantitative measurements and tabulates quantitative properties.

e-Lung focuses on what is visible to the eye and applies volumetric methods that might otherwise be too time consuming to use.

The software does not perform any function which cannot be accomplished by a trained user utilizing manual tracing methods; the software does not reconstruct a 3D rendering image of the lung; the intent of the software is to enhance the workflow by saving time and automating potential error prone manual tasks.

e-Lung has functions for loading, analyzing, and saving datasets, and will generate screen displays, computations and aggregate statistics. e-Lung data output may be exported to a CSV, Excel or PDF file.

3. Intended Use / Indications for Use

The e-Lung software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support in the examination of radiological findings. These radiological findings can then be evaluated by the physician in conjunction with a range of ancillary information to form a potential diagnosis or list of likely diagnoses. The e-Lung software package is intended to be a workflow enhancement and visualization tool for the assessment of CT thoracic datasets. e-Lung can be used to support the physician when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets. 3D segmentation, volumetric measurements, density evaluations, and reporting tools are combined with a dedicated workflow.

4. Performance Data

e-Lung complies with DICOM (Digital Imaging and Communications in Medicine) – developed by the American College of Radiology and the National electrical Manufacturers Association. NEMA PS 3.1 – 3.20.

The lung segmentation performance of the updated algorithm was validated through a head-to-head comparison between proposed and predicate devices. The study evaluated the accuracy of the e-Lung lung mask generation compared to a ground truth mask generated from the consensus of three experienced US board certified radiologists, who segmented the lungs following their usual standard of care. It was demonstrated that the Dice Similarity Coefficient (DSC) values were significantly higher

for the AI/ML segmentation algorithm method (proposed device) than the segmentation method of the predicate device (V=11628, p<0.0001) (see Figure 1). Furthermore, the clinical study also entailed a secondary objective, which was to demonstrate that device generalizability across a range of clinically relevant parameters, including demographics, clinical variables (BMI, smoking status, radiological findings) and scanner or image variables (location, scanner manufacturer, slice thickness, KvP and reconstruction method) was not impacted by the changes to the algorithm. It was concluded that the proposed device's AI/ML segmentation algorithm works effectively across all patient types.

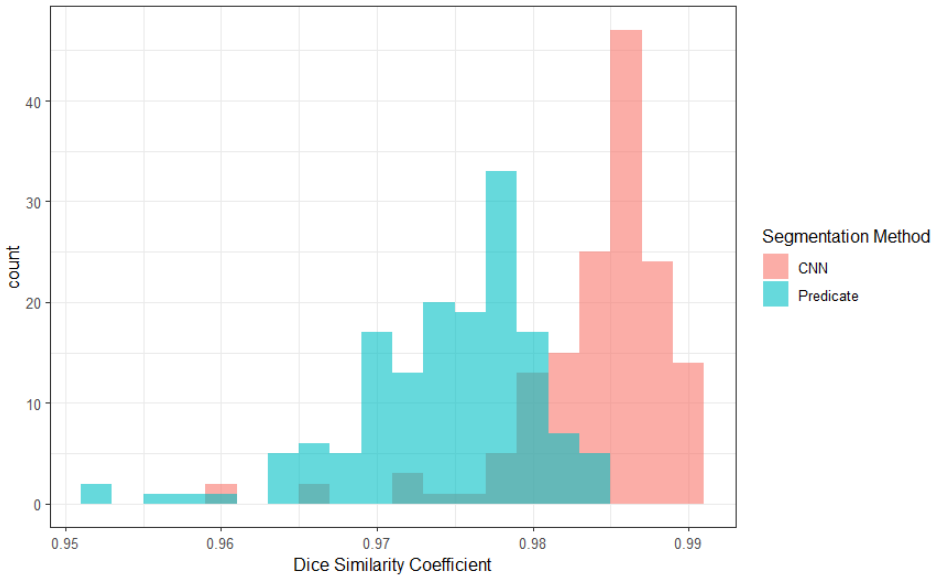

Figure 1. Histogram showing the distribution of Dice Similarity Coefficients (DSC) for the lung images segmented using the AI/ML segmentation algorithm (pink) vs the predicate segmentation algorithm (blue).

The longitudinal assessment feature and outputs to PACS and cloud were thoroughly verified as part of the software verification and validation activities. Software performance, validation and verification testing demonstrated that e-Lung met all design requirements and specifications.

5. Prescriptive Statement

Caution: Federal law restricts this device to sale by or on the order of a physician.

6. Safety and Effectiveness

Brainomix 360 e-Lung has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with ISO 14971:2019 (risk management).

7. Cybersecurity

Brainomix 360 e-Lung has been designed to follow the FDA Cybersecurity Guidance and IEC 81001-5-1.

8. Summary of Technological Characteristics

Brainomix 360 e-Lung principal workflow for chest CT datasets includes the following key steps:

1. Chest CT images loading. Brainomix 360 e-Lung provides an automated workflow which will automatically process image data received by the system.
2. Image processing function. Brainomix 360 e-lung processes chest CT scans and first generates a lung mask followed by any structural density filters or density histogram filters that have been pre-configured by an admin user.
3. Generation of summary results report
4. Image and results viewing. This is a non-diagnostic DICOM application allowing a trained clinician to view the CT image and associated results within the web UI. Results can also be sent and reviewed in PACS. The user is then able to edit the periphery of the lungs for that case and view updated quantifications. If multiple scans are available for a patient, images and results can be viewed simultaneously. These results may then be evaluated in conjunction with a range of ancillary information as part of the patient pathway.

Brainomix 360 e-Lung includes similar chest CT processing features and technological characteristics as compared to the predicate device. The intended use and principles of operation of the subject device are the same as those of the predicate device. There are no changes to the predicate e-Lung implementation that change the previously cleared features. Significant differences between the subject and predicate e-Lung devices are as follows:

- Improved algorithm for lung segmentation (AI/ML algorithm)
- Automated grouping of scans that have had the same workflow applied and calculation of differences in density evaluations between CTs (longitudinal assessment feature)
- Outputs in PACS and Cloud

Furthermore, minor improvements were also carried out with the aim of increasing the user's comfort when interacting with the device by providing additional PACS/DICOM viewing functionalities of adjustable slab thickness reconstructions, ability to view scans at original resolution and dynamic MPR with cross hair. Minor changes also include improvements in the visualization of outputs, additional user-defined options in relation to the structural density filters and improvement to the radiologist workflow by enabling networking and linking cases.

9. Clinical Characteristics

Brainomix 360 e-Lung can be used to support the physician when examining the pulmonary and thoracic tissue by providing quantifications of radiographic features through density evaluations and volumetric measurements including lung volume derived from a segmentation of the lungs.

Quantification of these features provides additional objective and reproducible data which can be used by physicians in addition to the current standard of care to aid diagnosis and longitudinal assessment of lung disease.

10. Substantial Equivalence

A table comparing the key features of the proposed and predicate device is provided below.

Characteristics/ Parameter	Proposed Device Brainomix 360 e-Lung	Predicate Device Brainomix 360 e-Lung	Comparison
510(k) Number	K242411	K233875	N/A
Product Code	JAK	JAK	Identical
Regulation Number	21 CFR §892.1750	21 CFR §892.1750	Identical
Regulation Name	System, X-Ray, Tomography, Computed	System, X-Ray, Tomography, Computed	Identical
Intended Use/Indications for Use	The e-Lung software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support in the examination of radiological findings. These radiological findings can then be evaluated by the physician in conjunction with a range of ancillary information to form a potential diagnosis or list of likely diagnoses. The e-Lung software package is intended to be a workflow enhancement and visualization tool for the assessment of CT thoracic datasets. e-Lung can be used to support the physician when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets. 3D segmentation, volumetric measurements, density evaluations, and reporting tools are combined with a dedicated workflow.	The e-Lung software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support in the examination of radiological findings. These radiological findings can then be evaluated by the physician in conjunction with a range of ancillary information to form a potential diagnosis or list of likely diagnoses. The e-Lung software package is intended to be a workflow enhancement and visualization tool for the assessment of CT thoracic datasets. e-Lung can be used to support the physician when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets. 3D segmentation, volumetric measurements, density evaluations, and reporting tools are combined with a dedicated workflow.	Identical
Image Source Modalities	CT	CT	Identical
DICOM Conformance	Yes	Yes	Identical
Interface Output	Web UI, PACS and cloud	Web UI	Different
Comparative Review	2D	2D	Identical
3D Lung Mapping	No	No	Identical

Characteristics/ Parameter	Proposed Device Brainomix 360 e-Lung	Predicate Device Brainomix 360 e-Lung	Comparison
3D Measurements	3D volume of masks	3D volume of masks	Identical
2D Measurements	None	None	Identical
Density Measurements	Admin user defined density histogram evaluation and structural density filtering evaluation	Admin user defined density histogram evaluation and structural density filtering evaluation	Identical
Deployment	Standard off-the-shelf server or virtual server	Standard off-the-shelf server or virtual server	Identical
OS	Ubuntu Linux	Ubuntu Linux	Identical
User Interface	Yes	Yes	Identical
Algorithm	Each voxel of the scan is measured by Hounsfield Units (HU), a measurement of x-ray attenuation that is applied to each volume element in three-dimensional space ('voxel'). The HU are utilized to distinguish between air, water, tissue and bone, such distinction is common in the industry. An AI/ML image processing approach is applied to CT imaging data to automatically segment lung mask.	Each voxel of the scan is measured by Hounsfield Units (HU), a measurement of x-ray attenuation that is applied to each volume element in three-dimensional space ('voxel'). The HU are utilized to distinguish between air, water, tissue and bone, such distinction is common in the industry. A (non-AI) image processing approach is applied to CT imaging data to automatically segment lung mask.	Similar, both devices segment a lung mask, however, the proposed device utilizes an AI/ML algorithm to perform this task
Workflow	Automated segmentation Automated measurements (including those based on user configurations) Automated grouping of scans from the same patient and automated measurements	Automated segmentation Automated measurements (including those based on user configurations)	Similar, added longitudinal assessment feature (grouping of scans from the same patient)
Graphic User Interface	Yes	Yes	Identical
Interactive 3D Visualization	No	No	Identical
Input/Output	Users can browse, select, and load CT scan files. Users can save and load analyses, export via reporting tools. CT scan files are organized by patient in the scan viewer. User can generate a report that displays quantitative data items that can be saved. DICOM info displayed. Data import through DICOM query/retrieve available.	Users can browse, select, and load CT scan files. Users can save and load analyses, export via reporting tools. CT scan files are organized by patient in the scan viewer. User can generate a report that displays quantitative data items that can be saved. DICOM info displayed. Data import through DICOM query/retrieve available.	Identical
Path Planning	No	No	Identical
User Editing	Yes	Yes	Identical
Reports	Yes – CSV, Excel and PDF format	Yes – CSV, Excel and PDF format	Identical

Characteristics/ Parameter	Proposed Device Brainomix 360 e-Lung	Predicate Device Brainomix 360 e-Lung	Comparison
Scan Quality Assessment	• Scan protocol is assessed for compatibility with software • Incompatibility issues flagged during import and on report	• Scan protocol is assessed for compatibility with software • Incompatibility issues flagged during import and on report	Identical

Table 1. Comparison of the key features of the subject and predicate device.

11. Conclusion

Brainomix 360 e-Lung includes similar chest CT processing features and technological characteristics as compared to the predicate device. The intended use and principles of operation of the subject device are the same as those of the predicate device. The differences in technological characteristics for the proposed device do not raise different questions of safety or effectiveness.

The proposed device does not raise different questions of safety and efficacy and demonstrates substantial equivalence to the predicate, Brainomix 360 e-Lung (K233875).