December 19, 2025

Topia MedTech Limited
Akshay Sojitra, Director
14 Havelock Place (MS)
Harrow, London HA11LJ
United Kingdom

Re: K252670
Trade/Device Name: Alzevita
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 3, 2025
Received: November 3, 2025

Dear Akshay Sojitra:

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,

Daniel M. Krainak, PhD
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

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.

510(k) Number *(if known)*
K252670

Device Name
Alzevita

Indications for Use *(Describe)*
Alzevita is intended for use by neurologists and radiologists experienced in the interpretation and analysis of brain MRI scans. It enables automated labelling, visualization, and volumetric measurement of the hippocampus from high-resolution T1-weighted MRI images. The software facilitates comparison of hippocampal volume against a normative dataset derived from MRI scans of healthy control subjects aged 55 to 90 years, acquired using standardized imaging protocols on 1.5T/3T MRI scanners.

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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Alzevita 510(k) Premarket Submission	
Revision: 03	**Date:** DEC 19,2025

510(k) Summary

I. Submitter

Name	TOPIA MEDTECH LIMITED
Address	14 Havelock Place (MS), Harrow, United Kingdom, HA11LJ
Contact Person	Akshay Sojitra
Telephone Number	+44 2081530878
Email	regulatory@topiamedtech.com

II. Device

Device Trade Name	Alzevita
Common Name	Medical Image Processing Software
Classification Name	Medical Image Management and Processing System
Regulation Number	21 CFR 892.2050
Regulation Description	Picture Archiving and Communications System
Product Code	QIH
Classification Panel	Radiology

III. Predicate Device

Device	NEUROShield
510(k) Number	K220034
Manufacturer	In Med Prognostics L3C
Product Code	LLZ

IV. Device Description

Alzevita is a cloud-based, AI-powered medical image processing software as a medical device intended to assist neurologists and radiologists with expertise in the analysis of 3D brain MRI scans. The software performs fully automated segmentation and volumetric quantification of the hippocampus, a brain structure involved in memory and commonly affected by neurodegenerative conditions.
Alzevita is designed to replace manual hippocampal segmentation workflows with a fast, reproducible, and standardized process. It provides quantitative measurements of hippocampal volume, enabling consistent outputs that can assist healthcare professionals in evaluating structural brain changes.

The software operates through a secure web interface and is compatible with commonly used operating systems and browsers. It accepts 3D MRI scans in DICOM or NIfTI format and displays the MRI image in the MRI viewer allowing trained healthcare professionals to view, zoom, and analyze the MRI scan alongside providing a visual and tabular volumetric analysis report.

The underlying algorithm used in Alzevita is locked, meaning it does not modify its behavior at runtime or adapt to new inputs. This ensures consistent performance and reproducibility of results across users and imaging conditions. Any future modifications to the algorithm including performance updates or model re-training will be submitted to the FDA for review and clearance prior to deployment, in compliance with FDA regulatory requirements and applicable guidance for AI/ML-based SaMD.

V. Indications for Use

Alzevita is intended for use by neurologists and radiologists experienced in the interpretation and analysis of brain MRI scans. It enables automated labelling, visualization, and volumetric measurement of the hippocampus from high-resolution T1-weighted MRI images. The software facilitates comparison of hippocampal volume against a normative dataset derived from MRI scans of healthy control subjects aged 55 to 90 years, acquired using standardized imaging protocols on 1.5T/3T MRI scanners.

VI. Comparison of Technological Characteristics with the Predicate Device

Details	Subject Device	Predicate Device	Remark
Name of Manufacturer	TOPIA MEDTECH LIMITED	In Med Prognostics L3C	-
Address of Submitter	14 Havelock Place (MS), Harrow, United Kingdom, HA11LJ	4918 September Street, San Diego, CA 92110, USA	-
Brand Name	Alzevita	NEUROShield	-
510 (K) Number	K252670	K220034	-
Generic Name	Medical Image Processing Software	Medical Image Processing software	Equivalent
Classification	Class II	Class II	Equivalent
Classification Product Code	QIH	LLZ	Substantially Equivalent
Intended Use	Alzevita is intended for use by neurologists and radiologists	The NEUROShield medical image processing software is intended for	Substantially Equivalent

	experienced in the interpretation and analysis of brain MRI scans. It enables automated labelling, visualization, and volumetric measurement of the hippocampus from high-resolution T1-weighted MRI images. The software facilitates comparison of hippocampal volume against a normative dataset derived from MRI scans of healthy control subjects aged 55 to 90 years, acquired using standardized imaging protocols on 1.5T/3T MRI scanners.	automatic labelling, visualization, and volumetric quantification of the Hippocampus brain structure from a set of MR images	
Design and Incorporated Technology	• A Software as a Medical Device (SaMD) designed for imaging and quantitative analysis of the hippocampal brain structure from MRI scans. • It is a fully automated, geometry-based brain analytics tool and cloud platform developed using advanced 3D U-Net++ methodologies	• Software as a medical device to be used in the process of Imaging and quantification of the Hippocampus brain structure from a set of MR images • Fully automated brain geometry - based quantifying analytics tool/cloud platform developed using DeepNet / U-Net methodologies	Substantially Equivalent
Physical Characteristics	• Software Package (Accessible via Web Browser) • Operates on off the shelf hardware (multiple vendors)	• Software Package (Accessible via Web Browser) • Operates on off the shelf hardware (multiple vendors)	Equivalent
Supported Operating Systems	Supports Linux, Windows and Mac OS latest	Supports Windows and Mac OS latest	Equivalent
Data Source	Alzevita requires compressed DICOM files or NIFTI files as Input	NEUROShield requires uncompressed DICOM files as input	Equivalent
Output	Software provides volumetric measurements of Hippocampus brain structures	Provides volumetric measurements of Hippocampus brain structures	Equivalent
Safety	• Automated quality control functions - Scan protocol verification • Results must be reviewed by a trained clinicians/ Radiologist/ Neurologist	• Automated quality control functions - Scan protocol verification • Results must be reviewed by a trained clinicians/ Radiologist/ Neurologist	Equivalent

VII. Performance Testing

Alzevita is a deep learning algorithm-based device. This algorithm is developed by training the Deep Learning based 3D U-Net++ model with the help of the training data.

Specifications of the Training dataset

Data is collected from India, between May 2024 to July 2025. The training dataset, consisting of 200 cases, is meticulously curated by considering various factors such as image variance, and quality. All cases are acquired using a 1.5 Tesla MRI scanner. Expert radiologists manually segmented the hippocampus to create the ground truth, which is then used as input for training the Alzevita segmentation model.

Table 1 presents the distribution of subjects based on key imaging and demographic parameters.

Subgroups		**Count**
Magnetic field strength	1.5T	200
Slice thickness	1	200
Equipment	GE	200
Gender	Male	110
	Female	90

Validation Study:

The performance of Alzevita is evaluated by a validation study summarized as follows:

A. Data Description

The performance validation dataset is collected from the publicly available ADNI (Alzheimer's Disease Neuroimaging Initiative) dataset. This dataset is independent of the training data and is not used to develop Alzevita's algorithm.

- Data Size: 298 subjects
- Study Type: Analytical & Cross-Sectional
- Data collection type: Retrospective
- Data Sampling: Stratified Random Sampling
- Recruitment factors: ADNI 1 & ADNI 3 dataset (Alzheimer's Disease Neuroimaging Initiative)
- MRI Equipment manufacturers: GE medical systems, Philips medical systems, Siemens Healthineers
- Magnetic Field Strength: 1.5T and 3T
- MRI Sequences/ protocol: 3D T1 MPRAGE
- Slice thickness: 1, 1.2
- Approximately equal geographical distribution in USA: East coast, Central US regions, West coast and Canada

The distribution for age bands is as follows:

The mean age of subjects is found to be 76 ± 7 years.

Age group	Count
55-64	20
65-69	37
70-74	74
75-79	82
80-84	58
85-90	27

The table below provides the categorization of subjects according to selection criteria:

Subgroups		Count	Mean (mL)	Standard deviation (mL)
Clinical Sub- groups	ADNI-control	132	7.0	1.0
	ADNI-MCI	103	5.6	1.3
	ADNI-AD	63	4.9	0.9
Gender	Male	150	5.8	1.3
	Female	148	6.4	1.4
Magnetic field strength	1.5T	128	5.5	1.3
	3T	170	6.05	1.1
Slice thickness	1	126	6.9	1.3
	1.2	172	5.6	1.3
Region	East USA	133	6.1	1.4
	West USA	56	6.2	1.5
	Central USA	90	6.2	1.4
	Canada	19	6.3	1.5

B. Ground Truth

i. A consensus ground truth is established through manual segmentation of MRI brain scans from 298 subjects. This task is performed by three certified radiologists in India, adhering to widely recognized and standardized segmentation protocols. The individual delineations are subsequently integrated into a single consensus mask for each case utilizing the STAPLE (Simultaneous Truth and Performance Level Estimation) algorithm. The reliability and accuracy of the consensus ground truth are statistically validated by comparing it with the individual segmentations done by the radiologists.

ii. The Alzevita algorithm performed automated segmentation of the hippocampal brain structure across all subjects, generating labelled segmentations with precise anatomical markings and calculating hippocampal volumes using advanced algorithmic techniques.

C. Statistical Analysis

Ground Truth Validation: Using the Dice coefficient, and Hausdorff distance, the STAPLE-derived ground truth (via ITK-SNAP) is validated through comparison with segmentations from three radiologists. Statistical analysis indicated no significant discrepancies ($p > 0.05$) between these individual segmentations and the consensus ground truth, thereby substantiating the consistency of the radiologist annotations and the reliability of the ground truth itself.

i. Geometric comparison of Alzevita with Ground Truth: An evaluation of Alzevita's automated hippocampus segmentations is conducted by comparing them to the STAPLE-derived ground truth, utilizing Dice scores and Hausdorff distance as quantitative measures. The algorithm's performance met the established criteria for both metrics, signifying a high level of geometric correspondence with the annotations provided by expert radiologists.

ii. Quantitative Volume Comparison: A comparison is made between hippocampal volumes derived from the STAPLE ground truth and those generated by Alzevita. Utilizing correlation analysis, Bland-Altman (BA) plots, and relative volume difference, Alzevita successfully met the criteria across all three statistical evaluation methods, demonstrating strong agreement between the hippocampal volumes computed by Alzevita and those derived from the STAPLE consensus ground truth.

iii. Pass/Fail criteria: The Alzevita algorithm met all predefined performance thresholds, demonstrating its accuracy and reliability in hippocampal segmentation and volume estimation:

- Dice Score: ≥ 75%
- Hausdorff Distance: ≤ 6.1 mm
- Correlation Coefficient: ≥ 0.82
- Relative Volume Difference: ≤ 24.6%
- Bland-Altman Mean Difference (Total Hippocampus Volume): ≤ 1010 mm^3

These results validate the robustness of the algorithm's automated segmentation and volume computation capabilities.

iv. Subgroup Error Analysis: Subgroup analyses are conducted across variations such as magnetic field strength, gender, slice thickness, clinical subgroups, and geographic regions within the U.S. In all cases, Dice scores exceeded 83%, and Hausdorff distances remained below 3 mm, indicating consistently high segmentation accuracy. Additionally, Alzevita met the criteria for both correlation and relative volume difference across all subgroups, demonstrating robustness and generalizability of the model.

D. Results

i. The average dice coefficient and Hausdorff distance is found to be 0.86 and 1.51 mm respectively. The following table shows the 95% confidence interval for both.

Measure	**Threshold**	**Alzevita 95 % confidence intervals**	**Criteria (Pass/Fail)**
Dice	0.75	(0.85, 0.86)	Pass
Hausdorff distance	6.1	(1.43, 1.59)	Pass

ii. The outcomes of subgroup error analysis are as follows:

a) Clinical subgroups

	Dice Score			**Hausdorff Distance (mm)**		
Clinical subgroups	Control	MCI	AD	Control	MCI	AD
Measured value	0.88	0.85	0.83	1.36	1.53	1.79
Alzevita 95 % confidence intervals	(0.87, 0.88)	(0.84, 0.85)	(0.82, 0.84)	(1.32, 1.41)	(1.44, 1.62)	(1.48, 2.10)
Criteria	Pass	Pass	Pass	Pass	Pass	Pass

b) Gender

	Dice score		Hausdorff Distance (mm)	
Gender	Female	Male	Female	Male
Measured value	0.86	0.85	1.48	1.54
Alzevita 95 % confidence intervals	(0.85, 0.87)	(0.84, 0.86)	(1.40, 1.57)	(1.41, 1.66)
Criteria	Pass	Pass	Pass	Pass

c) Magnetic field strength

	Dice score		Hausdorff Distance (mm)	
MRI strength	3T	1.5T	3T	1.5T
Measured value	0.87	0.84	1.43	1.62
Alzevita 95 % confidence intervals	(0.86, 0.87)	(0.83, 0.85)	(1.38, 1.47)	(1.45, 1.79)
Criteria	Pass	Pass	Pass	Pass

d) Slice Thickness

	Dice score		Hausdorff Distance (mm)	
Slice thickness	1 mm	1.2mm	1 mm	1.2mm
Average value	0.87	0.84	1.39	1.60
Alzevita 95 % confidence intervals	(0.87, 0.88)	(0.84, 0.85)	(1.35, 1.43)	(1.47, 1.72)
Criteria	Pass	Pass	Pass	Pass

e) US Geographical Region

	Dice score				Hausdorff Distance (mm)			
Region	East US	West US	Central US	Canada	East US	West US	Central US	Canada
Average value	0.85	0.86	0.86	0.85	1.57	1.45	1.41	1.71
Alzevita 95 % confidence intervals	(0.84,0.86)	(0.85, 0.87)	(0.85, 0.87)	(0.82, 0.88)	(1.44,1.71)	(1.35,1.55)	(1.35, 1.47)	(1.07, 2.34)
Criteria	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Performance analysis of Alzevita for hippocampus segmentation revealed consistently strong results, with overall Dice scores surpassing 83% and Hausdorff distances remaining under 3 mm. Such outcomes affirm the algorithm's high accuracy and reliability, substantiating its precision in both structural correspondence and relative hippocampal volume assessment.

VIII. Conclusions

The evaluation provides objective evidence supporting the reliability, accuracy, and reproducibility of Alzevita for automated hippocampal segmentation. Validation and performance testing demonstrate that the device meets predefined acceptance criteria for its intended use in clinical neuroimaging workflows. The results support the device's suitability for use by qualified healthcare professionals in the assessment of neurological structures. Furthermore, Alzevita has been demonstrated to be substantially equivalent to its predicate device, NEUROShield (K220034), with respect to intended use, technological characteristics, and performance.