VinBrain Joint Stock Company
Steven Quoc Hung Truong
Chief Executive Officer
No 7 Bang Lang 1 Street, Vinhomes Riverside Ecological
Urban Area, Long Bien District
Hanoi, 100000
Vietnam

December 6, 2024

Re: K241543
Trade/Device Name: DrAid™ for Liver Segmentation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: November 7, 2024
Received: November 7, 2024

Dear Steven Quoc Hung Truong:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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)*
K241543

Device Name
DrAid™ for Liver Segmentation

Indications for Use *(Describe)*
DrAid™ for Liver Segmentation is a web-based software, non-invasive image analysis application designed for the visualization, evaluation, and reporting of liver and physician identified lesions using multiphase images (with slice thickness <= 3.0mm) of patients aged and older than 22 years old obtained from CT scanners. The software provides a range of tools for image viewing, processing, and reporting.
The software enables professionals, including physicians and technicians, to review and analyze multiphase volume datasets of the liver. DrAid™ for Liver Segmentation operates in a semiautomated quantitative imaging function, utilizing an Al algorithm to generate liver segmentation that is then editable by the physician if necessary. Additionally, the device provides tools for manual segmentation within user input of seed points and boundary editing for physician-identified lesions within the liver. Professionals can assess liver volume (mm^3), liver lesion volume (mm^3), and maximum lesion diameter (mm), position, thereby aiding in evaluation and treatment planning.
It is important to note that the software is intended for use by trained professionals, including physicians and technicians. The image source for analysis is DICOM, allowing compatibility with standard medical imaging data formats.

Note: DrAid™ for Liver Segmentation does not generate diagnoses or potential findings directly.
The interpretation of the image data and the clinical decision-making process should be performed by qualified healthcare professionals. The installation and deployment of the software medical device should be carried out by VinBrain and trained technicians.
Caution: Federal law restricts this device to sale by or on the order of a physician.

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.

K241543

510(k) Summary

DrAid™ for Liver Segmentation

Name and Address of Applicant: VinBrain Joint Stock Company
No 7 Bang Lang 1 Street,
Vinhomes Riverside Ecological Urban Area,
Viet Hung Ward, Long Bien District,
Hanoi, 100000, Vietnam

Contact Person: Steven Quoc Hung Truong , Chief Executive Officer
Telephone No.: 84 (981) 927-516
Email Address: anh3.pham@vinbrain.net

Date of Submission: November 7, 2024

Device Name: DrAid™ for Liver Segmentation

Product Code: QIH

Regulation Name: Medical image management and processing system

Regulation Number: 892.2050

Classification: Class II

Classification Name: System, Image Processing, Radiological

Identification of Predicate Device:

510(k) Number: K131498

Device Name: IQQA-LIVER MULTIMODALITY SOFTWARE

Manufacturer: EDDA TECHNOLOGY, INC.

1. Device Description Summary

Device Identification:

Key device components:

- - AI algorithm for liver segmentation
- - Measurement algorithm
- - DICOM Processing Module for CT images
- - Liver Segmentation viewer
- - Results Export Module
- Device Characteristics:
- Software

Environment of Use:

- Healthcare facility/hospital

Brief Written Description:

- Explanation of how the device works/principle of operation: DrAid™ for Liver Segmentation is a web-based software that processes and analyzes multiphase CT images in DICOM format. The software utilizes AI algorithms for semi-automated liver segmentation, combined with manual editing capabilities. Additionally, the device provides tools for manual segmentation

with user input of seed points and boundary editing for physician-identified lesions within the liver.

- Key Features for SE/Performance:
  - Visualization modes:
    - Original DICOM 2D image viewing
    - MPR visualization
  - Manual correction tools:
    - Seed point placement
    - Boundary editing for lesions
    - Segmentation refinement
  - Reporting tool.
- Energy Source:
  - Web-based application running on standard hospital/clinic workstations

2. Indications for use

DrAid™ for Liver Segmentation is a web-based software, non-invasive image analysis application designed for the visualization, evaluation, and reporting of liver and physician identified lesions using multiphase images (with slice thickness <= 3.0mm) of patients aged and older than 22 years old obtained from CT scanners. The software provides a range of tools for image viewing, processing, and reporting.

The software enables professionals, including physicians and technicians, to review and analyze multiphase volume datasets of the liver. DrAid™ for Liver Segmentation operates in a semiautomated quantitative imaging function, utilizing an Al algorithm to generate liver segmentation that is then editable by the physician if necessary. Additionally, the device provides tools for manual segmentation within user input of seed points and boundary editing for physician-identified lesions within the liver. Professionals can assess liver volume (mm^3), liver lesion volume (mm^3), and maximum lesion diameter (mm), position, thereby aiding in evaluation and treatment planning.

It is important to note that the software is intended for use by trained professionals, including physicians and technicians. The image source for analysis is DICOM, allowing compatibility with standard medical imaging data formats.

Note: DrAid™ for Liver Segmentation does not generate diagnoses or potential findings directly.

The interpretation of the image data and the clinical decision-making process should be performed by qualified healthcare professionals. The installation and deployment of the software medical device should be carried out by VinBrain and trained technicians.

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

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3. Indication for use comparison

Both the subject and predicate devices are intended for segmentation of liver and physician identified lesions for use by trained healthcare professionals and are compatible with DICOM image data, which is essential for medical imaging applications.

4. Technological comparison

Technical comparison with predicate device:

Both the subject and predicate device are software applications, supporting the evaluation of liver lesions from multiphase images and provide essential tools for image viewing, segmentation, and reporting. Both are designed for use by trained healthcare professionals and intended for use in a hospital healthcare environment. The differences in deployment platforms, liver segmentation technology, operating systems and some features do not compromise the safety and effectiveness of either device in their intended clinical applications.

The subject device provides semi-automatic segmentation of the liver using an AI algorithm with editable tool, whereas the predicate device provides manual segmentation for liver. The difference in liver segmentation techniques highlights the strength of DrAid™ for Liver Segmentation in leveraging an AI algorithm for liver segmentation. The utilization of advanced algorithms can enhance the efficiency and accuracy of liver segmentation. The difference in segmentation techniques does not raise different questions regarding the safety and effectiveness of DrAid™ for Liver Segmentation.

5. Non – Clinical and/or Clinical Test summary & conclusions

DrAid™ for Liver Segmentation has been rigorously evaluated and verified to align with user needs and intended applications through successful performance, functionality, and algorithmic tests. Testing outcomes confirm that DrAid™ for Liver Segmentation fulfills the device's user needs and requirements, demonstrating substantial equivalence in performance to the listed predicate and reference devices.

Performance testing was performed using the representative and independent US dataset and, to ensure that the performance and accuracy met the requirements and standards. The ground truth was established by the annotations provided by 3 US board-certified radiologists.

Overall Liver Segmentation Algorithm:

- Patients:
    - 450 contrast-enhanced CT scans of 150 patients
    - Age distribution: 60 ±12
    - Sex distribution: 49.3% female, 50.7% male
    - Location of clinical sites: US medical institutions
    - Image procedure: Contrast-enhanced CT images taken for diagnostic reading

The following table provides a summary of the validation results:

Test performed	Sample size (number of CT scans)	Acceptance criteria	Performance results
Liver segmentation mask	450	1) Mean Dice ≥ 0.95 2) 95% CI lower bound of Dice scores ≥ 0.90 3) 95% CI upper bound of HD95 score ≤ 4.0	1) Dice score: + Mean 1std: 0.9649 0.0195 + 95% CI Dice: 0. 9649 [0.9631, 0.9667] 2) HD95: + Mean 1std: 1.70611.5800 + 95% CI: 1.7061 [1.5595, 1.8526]

It is evident that the performance of the DrAid™ liver segmentation algorithm evaluated on the representative test set meets the aforementioned acceptance requirements. The performance observed on the US-patient dataset, encompassing diverse tumors, steatosis cases, cirrhosis cases, and hepatomegaly demonstrates the algorithm's robustness when confronted with challenging data.

The results of the liver volume measurement are provided below.

Test performed	Sample size(number of CT scans)	Acceptance criteria	Performance results
liver volume measurement	450	95% CI upper bound of Volume Error ≤ 5%	NVE: Mean 1std: 2.7269 % 3.1928 % 95% CI: [2.4308 % , 3.0230 %]

Furthermore, we evaluated the AI algorithm on main subgroups (i.e., different types of abnormalities, age groups, gender groups, phase groups, and ethnicity groups) to prove the model generalization capability on diversity data distributions. Detailed subgroup analysis is reported in the labeling.

The generalization capability of the DrAid™ liver segmentation algorithm is also verified using datasets collected from a wide range of CT scan manufacturers used in practical clinics. Details on the scanner types, data distribution, and performance results given in the table below demonstrate the robustness of the subject device to the different data sources acquired from the diverse manufacturers.

CT brand	CT model name	Number of scans	Data source	Mean Dice [95% CI]
Siemens	SOMATOM go.Up	450	USA	0.9649 [0.9631, 0.9667]
GE Medical Systems	LightSpeed 16, LightSpeed VCT, Revolution ACT	30	USA	0.9786 [0.9759, 0.9812]
Philips	Brilliance 64	30	USA	0.9747 [0.9726, 0.9768]

Toshiba	Aquilion ONE	30	Vietnam	0.9760 [0.9712, 0.9809]

Conclusion:

In conclusion, all verification and validation activities demonstrated that the design specifications and technological characteristics of DrAid™ for Liver Segmentation meet the applicable requirements and standards and DrAid™ for Liver Segmentation is substantially equivalent to the currently marketed predicate device.