



July 10, 2019

Deep01 Limited
% Mr. William Lai
Medical Regulatory Affairs Specialist
Rm. 5, 11F., No.162, Sec. 4, Roosevelt Rd.
Taipei City, Taiwan 10091
TAIWAN

Re: K182875

Trade/Device Name: DeepCT
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: June 7, 2019
Received: June 7, 2019

Dear Mr. Lai:

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 (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 located 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.

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 803) for

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

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

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182875

Device Name

DeepCT

Indications for Use (Describe)

DeepCT is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

DeepCT uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes non-contrast CT images of the brain acquired in the acute setting and sends notifications to a specialist that a suspected ICH (intracranial hemorrhage) has been identified and recommends review of those images.

Notified clinicians are responsible for viewing non-contrast CT images of the brain on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating specialist before making care-related decisions or requests. DeepCT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DeepCT (Ver. 4.1.4)
510(k) Summary
K182875

I. SUBMITTER

Deep01 Limited

Rm. 5, 11F., No.162, Sec. 4, Roosevelt Rd.,
Taipei City 10091, Taiwan (R.O.C.)

Tel: +886-2-2365-9959

Contact Person: William Lai

Date Prepared: Sep 26, 2018

II. DEVICE

Name of Device: DeepCT

Common or Usual Name: Radiological Computer-Assisted Triage And
Notification Software

Classification Name: Radiological Computer-Assisted Triage And
Notification Software (21 CFR 892.2080)

Regulatory Class: II

Product Code: QAS

III. PREDICATE DEVICE

DEN170073, ContaCT

K180647, BriefCase

IV. DEVICE DESCRIPTION

This software is used to analyze the head computed tomography image of a patient suspected of having intracranial hemorrhage and/or hematoma (hereinafter referred to as "ICH"). Provide a "present" situation (with ICH) notification, send a text message to the user.

For example, after the finished CT scan of the patient, it will produce relevant CT information (including brain DICOM file). Relevant hospital personnel can use this software to perform AI analysis and interpretation of the DICOM file. During and after the software analysis, relevant hospital personnel can continue the general analysis procedure. If the result of the analysis is "present" (with ICH), relevant hospital personnel will receive a notification message. The use process is parallel to the

general medical treatment process and does not involve or affect patient care procedures.

When the software is not used, medical personnel perform a general image interpretation process. When using this software, medical personnel can refer to the interpretation results of this software and perform a general image interpretation process.

DeepCT (Ver. 4.1.4) is a software-only device that uses two components: (1) Image Forwarding Software and (2) Image Processing and Analysis Server.

(1) The Image Forwarding Software is configured by the hospital to be used on a computer and is responsible for transmitting a copy of DICOM files from the local through a secured channel to the Image Processing and Analysis Server.

When the Image Forwarding Software receives the interpretation result from the Image Processing and Analysis Server, it shows the result on the screen. If there is a suggestive of ICH, the Image Forwarding Software sends a notification to the specialist identifying the study of interest. While the software informs the notification process, no other diagnostic information is generated from the software or available to the user beyond the notification.

(2) The Image Processing and Analysis Server is responsible for receiving, assembling, processing, analyzing and storing DICOM images. This component includes the algorithm that is responsible for identifying and quantifying image characteristics that are consistent with a ICH and transmit the result back to the Image Forwarding Software.

Environment of Use: Hospital emergency room

The head CT scan is imaged as a series of DICOM data used as inputs for model training, performance validation and product qualification. The Tri-Service General Hospital Institutional Review Board, Kaohsiung Veterans General Hospital Institutional Review Board and National Taiwan University Hospital Research Ethics Committee all approved and consented the use of the retrospective image data for DeepCT development and deployment without relevant ethical concern. Radiology records were collected from 21,603 patients who underwent head CT scans between 2007 and 2017.

A deep residual convolutional neural network (aka Residual Network or ResNet for short, see Kaiming He et al. <https://arxiv.org/abs/1512.03385>)

was adopted as the core learning model. By repeatedly applying residual connection, the ResNet model can ease the training of networks that are substantially deeper, effectively help the convergence of the model and gain the accuracy with deep neural networks. The model was trained with a categorical cross-entropy loss with Adam optimizer. Data augmentation was introduced to motivate the model to learn the rotated and translated images. Our DeepCT system was trained with PyTorch, an open source deep learning software library (<https://pytorch.org>).

Same model with three different layer size, 18, 34, 52, respectively, were trained to cross evaluate the model performance. 34-layer Residual Network was chose as the final model since it got the best tradeoff between performance and computation complexity. We saw little performance gain by extending from 34 to 52 layers.

V. INDICATIONS FOR USE

DeepCT (Ver. 4.1.4) is notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

DeepCT (Ver. 4.1.4) uses an artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes non-contrast CT images of the brain acquired in the acute setting and sends notifications to a specialist that a suspected ICH has been identified and recommends review of those images.

Notified clinicians are responsible for viewing non-contrast CT images of the brain on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating specialist before making care-related decisions or requests. DeepCT (Ver. 4.1.4) is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

The Indications for Use statement for this device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The user will receive the message of the result of interpretation, and he/she must use computer (not mobile device) to check complete image to make independent diagnosis. By providing different training to the artificial intelligence, it will

perform different interpretation to different evaluation target in different image format.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Similarities:

Both ContaCT and DeepCT (Ver. 4.1.4):

Are to identify and communicate CT images of specific patients to a specialist, independent of standard of care workflow.

Use artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation and recommends review of those images.

Process images intended to aid in prioritization and triage of radiological medical images.

Are not for diagnostic use beyond notification.

Send notifications to a specialist. Those notifications work in parallel to the standard of care. They prompt the specialist to start preemptive triage of a notified case, upon which he may decide after observing the preview on his desktop, to turn to the local PACS to perform the evaluation. If a notification is rejected, the case still remains in the queue to be handled per the standard of care.

Are limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis; and,

Notified clinicians are responsible for viewing CT images of the brain on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating specialist before making care-related decisions or requests.

Differences:

ContaCT preview images through a mobile application while DeepCT (Ver. 4.1.4) does not.

This difference does not affect safety and effectiveness, since no matter which software the user use, the user will receive the message of the result of interpretation, and he/she must use computer (not mobile device) to check complete image to make independent diagnosis.

DeepCT (Ver. 4.1.4) interprets non-contrast CT images for suspected ICH, while ContaCT interprets CT angiogram images for suspected large vessel occlusion.

This is simply the difference in evaluation target and image format. Both of them are to interpret by artificial intelligence. By providing different training to the artificial intelligence, it will perform different interpretation to different evaluation target in different image format. This difference does not affect safety and effectiveness. The performance evaluation results show that the performance of the two is equivalent.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance Testing

Deep01 conducted a retrospective, multicenter, multinational study with the DeepCT software with the primary endpoint to evaluate the software's performance in identifying non-contrast CT head images containing ICH findings in 260 cases from 5 clinical sites (2 US and 3 OUS). There are 130 cases in US study and 130 cases in OUS study. There was approximately an equal number of positive and negative cases (images with ICH versus without ICH) included in the analysis.

Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was observed to be 93.8% (95% CI: 88.3%-96.8%) and specificity was observed to be 92.3% (95% CI: 86.4%-95.7%).

In addition, a secondary endpoint measure was DeepCT's processing time.

The DeepCT processing time includes the time from browsing and selecting dicom files to the notification of the interpretation result. DeepCT processing time has been documented for all 122 cases.

The processing time is 30.6 seconds (95% CI: 25.8-35.4 seconds), which is lower than the processing time reported by the Aidoc BriefCase device.

In summary, performance validation data establish the achievement of effective triage by the DeepCT image analysis algorithm as well as effective notification functionality of the DeepCT application.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

VIII. CONCLUSIONS

The performance data support the safety of the device and the software verification and validation demonstrate that the DeepCT (Ver. 4.1.4) device should perform as intended in the specified use conditions.