Medicalip Co., Ltd.
% Jonghyun Kim, CEO
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro, Mapo-gu
Mapo-gu
Seoul, 03909
KOREA

June 16, 2023

Re: K223556
Trade/Device Name: DeepCatch
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: May 17, 2023
Received: May 17, 2023

Dear Jonghyun Kim:

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 and Part 809); 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223556

Device Name
DeepCatch

Indications for Use *(Describe)*
DeepCatch analyzes CT images and auto-segments anatomical structures (skin, bone, muscle, visceral fat, subcutaneous fat, internal organs and central nervous system). Then, its volume and proportions are calculated and provided with the relevant 3D model.
By using DeepCatch, it is possible to obtain accurate values for the volume and proportion of each anatomical structures by secondary utilization of CT images obtained for various purposes in the medical field. The type of input data is whole body CT. This device is intended to be used in conjunction with professional clinical judgement. The physician is responsible for inspecting and confirming all results.

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

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

June 13, 2023

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: MEDICAL IP Co., Ltd.
- Address: SNUH Cancer Research Center 806, 101 Daehak-ro, Jongno-gu, Seoul, KR 0308
- Contact Name: Jun-sik Yoon
- Telephone No.: +82 10-8277-2909
- Email Address: jsyoon@medicalip.com
- Registration No.: 3016579137

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

510(k) Number	K223556
Trade/Device/Model Name	DeepCatch
Product Name	Picture archiving and communications system
Device Classification Name	Medical Image management and processing system
Regulation Number	21 CFR 892.2050
Classification Product Code	QIH
Device Class	II
510(k) Review Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

Predicate Device #1

510(k) Number	K191026
Trade/Device/Model Name	MEDIP PRO
Device Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Classification Product Code	LLZ
Device Class	II
510(k) Review Panel	Radiology

Predicate Device #2

510(k) Number	K130542
Trade/Device/Model Name	SYNAPSE 3D LUNG AND ABDOMEN ANALYSIS
Device Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Classification Product Code	LLZ
Device Class	II
510(k) Review Panel	Radiology

These predicate devices have not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

DeepCatch is medial image processing software that provides 3D reconstruction and visualization of ROI, advanced image quality improvement, auto segmentation for specific target, texture analysis, etc. Data that accurately analyzes the amount of skeletal muscle and adipose tissue distributed in the body in 3D can be used as base data in various fields.

6. Indications for use [21 CFR 807.92(a)(5)]

DeepCatch analyzes CT images and auto-segments anatomical structures (skin, bone, muscle, visceral fat, subcutaneous fat, internal organs and central nervous system). Then, its volume and proportions are calculated and provided with the relevant 3D model.

By using DeepCatch, it is possible to obtain accurate values for the volume and proportion of each anatomical structures by secondary utilization of CT images obtained for various purposes in the medical field. The type of input data is whole body CT. This device is intended to be used in conjunction with professional clinical judgement. The physician is responsible for inspecting and confirming all results.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate devices which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the DeepCatch and the predicate devices:

[Table 1. Comparison of Proposed Device to Predicate Devices]

Item	Proposed Device	Predicate Device #1	Predicate Device #2
K Number	K223556	K191026	K130542
Manufacturer	MEDICALIP CO., LTD.	MEDICALIP CO., LTD.	FUJIFILM MEDICAL SYSTEM U.S.A., INC.
Model Name	DeepCatch	MEDIP PRO	SYNAPSE 3D LUNG AND ABDOMEN ANALYSIS
Product Code	QIH	LLZ	LLZ
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Technological characteristics			
Indications for Use	DeepCatch analyzes CT images and auto-segments anatomical structures (skin, bone, muscle, visceral fat, subcutaneous fat, internal organs and central nervous system). Then, its volume and proportions are calculated and provided with the relevant 3D model. By using DeepCatch, it is possible to obtain accurate values for the volume and proportion of each anatomical structures by secondary utilization of CT images obtained for various purposes in the medical field. This device is intended to be used in conjunction with professional clinical judgement. The type of input data is whole body CT. The physician is responsible for inspecting and confirming all results.	MEDIP PRO is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file. It is also used as pre-operative software for treatment planning. The 3D printed models generated from the output file are meant for non-diagnostic use. MEDIP PRO should be used in conjunction with other diagnostic tools and expert clinical judgement.	Synapse 3D Lung and Abdomen Analysis is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, and treatment planning. Synapse 3D Lung and Abdomen Analysis accepts DICOM compliant medical images acquired from CT. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images. Addition to Synapse 3D Base Tools, Synapse 3D Lung and Abdomen Analysis is intended to: - use non-contrast and contrast enhanced computed tomographic images of the lung, provide custom workflows and UI, and reporting functions for lung analysis including boundary detection and volume calculation for pulmonary nodules in the lung based on the location specified by the user, segmentation of bronchial tubes in the lung, approximation of air supply region by the user specified bronchial tube, identifying,

Item	Proposed Device	Predicate Device #1	Predicate Device #2
			displaying and processing low absorption regions in the lung. - use non-contrasted CT images and calculate subcutaneous fat and visceral fat areas in 2D and both volumes in 3D. - analyze a bronchus path to reach a lung nodule using the volume data collected with CT, and simulate insertion of bronchoscope into the path.
Type of use	Prescription Use	Prescription Use	Prescription Use
User population	Clinical expert	Clinical expert	Clinical expert
Image Modalities	DICOM imaging information from CT	DICOM imaging information from CT, MRI	DICOM imaging information from CT
Feature/ Functionality	-Analysis & Measurement -2D/3D visualization -Segmentation -3D Rendering -Exporting CSV data -Calculation of BMI	-Analysis & Measurement -Image Enhancement -2D/3D visualization -Segmentation -3D Rendering -Exporting STL data for 3D Printing	-Analysis & Measurement -Image Enhancement -2D/3D visualization -Segmentation -3D Rendering -Export Report -Calculation of BMI -Abdominal Circumference
Segmentation Regions	Skin, Bone, Muscle, abdominal visceral fat, subcutaneous fat, internal organs, central nervous system	Skin, Bone, Muscle, abdominal visceral fat, subcutaneous fat, internal organs, central nervous system, Lung Pulmonary Vessel Liver Femur Etc. (Manual segmentation)	Visceral fat, Subcutaneous fat
Visualization/Edit Tools	*2D View -zoom in -zoom out * 3D View - Anterior -Posterior -Superior -Inferior -Right -Left -Smooth	*2D View -zoom in -zoom out * 3D View - Anterior -Posterior -Superior -Inferior -Right -Left -Smooth	*2D View -Cine Play -Switch display types -Real time stack reconstruction -Link coordinates -Capture slice -Browse study data -Image store and restore *3D View -2D cross section -Compare with past studies -Switch between SYNC/ASYNC -Series registration -Virtual endoscope
Data reporting	Yes	Yes	Yes

Item	Proposed Device	Predicate Device #1	Predicate Device #2
Export file formats	Yes	Yes	Yes

A detailed comparison shows the subject device is substantially equivalent in intended use, software type, modality support operating system, image communication standard and functionality to the predicate device. The subject device only intends to be a software for treatment planning and does not include the simulation of treatment options. The 3D printed models generated from the output file are meant for non-diagnostic use. The differences between the subject and predicate device do not raise any new questions regarding safety and effectiveness.

8. Non-Clinical Test summary

The DeepCatch complies with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Software Validation

The DeepCatch contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

2) Performance test

The DeepCatch application has been validated for its intended use to determine substantial equivalence to the predicate device. The device functionalities were performed, verified and validated to be within specification.

a) Performance test using data set from Korea (562) and France (18) with DeepCatch

Datasets	Items	Group	Null hypothesis	Alternative hypothesis
Internal Datasets (n=100)	**DSC**	DSC between 'GT' and 'segmentation results of DeepCatch'	Group's DSC mean is less than 0.900.	Group's DSC mean is greater than or equal to 0.900.
External Datasets (n=580)	**DSC**	DSC between 'GT' and 'segmentation results of DeepCatch'	Group's DSC mean is less than 0.900.	Group's DSC mean is greater than or equal to 0.900.
	Volume	Difference between 'GT' and 'measurement results of DeepCatch'	The mean of the within-group difference is greater than ±10% (0.10).	The mean of the within-group difference is less than ±10% (0.10).

	Area		The mean of the within-group difference is greater than ±10% (0.10).	The mean of the within-group difference is less than ±10% (0.10).
	Ratio		The mean of the within-group difference is greater than ±1% (0.01).	The mean of the within-group difference is greater than ±1% (0.01).
	Body Circumference		The mean of the within-group difference is greater than ±5% (0.05).	The mean of the within-group difference is less than ±5% (0.05).

In the internal datasets test, DSC means of GT and segmentation results of DeepCatch shows greater than or equal to 90%.

In the external data sets test, the DSC mean of GT and segmentation results of DeepCatch in all areas is more than 90%, the mean value of volume and area for the difference between GT and measurement results of DeepCatch is less than 10%, the mean value of ratio for the difference between GT and measurement results of DeepCatch is less than 1%, and body circuit reference mean value is less than 5%.

b) Performance test using data set from US-based locations with DeepCatch

To test that the performance associated with the safety and effectiveness of DeepCatch is not biased toward a particular population, we evaluated DeepCatch performance for Americans by designing the same as performance tests for Koreans and French. The following data sets were collected from East River Medical Imaging to perform DeepCatch performance tests. 167 CT images were collected using GE MEDICAL SYSTEMS. The average age of the collected data patients was 67.2±12.8 and had a male-female ratio of 83:84. The racial distribution was 123 Whites, 30 Blacks or African American, 2 American Indian and Alaska native, and 12 Asians. As a result, for all anatomical structures, DSC mean was more than 90%, volume and area were less than 10%, less than 1%, and error measurements for GT to abdominal circumference were less than 5%.

3) Comparative Performance Test

The DeepCatch engineers conducted a Comparative Performance Test for segmentation and measurement functionalities in the software with predicate device.

- Calculated quantitative results through DSC(Dice Similarity Coefficient).

a) Comparative Performance Test with MEDIP PRO

The performance tests were performed on the proposed and predicate devices to evaluate automatic segmentation accuracy. 100 whole body CT images were collected using two models (Siemens and Healthineers) of scanners available in the United States. The patients whose images were collected had an average age of 51.9±13.2 and a male-female ratio of 40:60. All data used images independent of the images used to learn the algorithm. Ground truthing for each image was created by a licensed physician. The evaluation used the DICE similarity factor. The DSC value was calculated on the equivalent of the proposed device. In addition, an

independent sample t-test was performed to determine whether there was a significant difference between the derived DSC values. Results showed that the DSC of DeepCatch was not inferior to that of MEDIP PRO. DeepCatch showed no difference in performance evaluations performed with MEDIP PRO, and showed better performance than MEDIP PRO for Muscle segmentation.

b) Comparative Performance Test with Synapse 3D

The performance tests were performed on the proposed device and predicate device to evaluate the accuracy of the volume and proportion calculations of the body circumference, SF and AVF. 100 whole-body CT images independent of MEDIP PRO comparison tests were collected using scanner models (Siemens and Healthineers) available in the United States. The patients whose images were collected had an average age of 52.2±12.4 and a male-female ratio of 64:36. All data used images independent of the images used to learn the algorithm. Ground truthing for each image was created by a licensed physician. The evaluation calculated the volume, ratio, area, and body circumference for each area. The calculated values were compared with GT. Furthermore, an independent sample t-test was performed to determine whether there was a significant difference between the derived values. As a result, DeepCatch showed no difference in performance test compared to synapse 3D, and showed better performance than Synapse 3D in AVF Area (AW) and SF Area (AW).

4) Cybersecurity

- "Content of Premarket Submission for Management of Cybersecurity in Medical Devices.", on October2, 2014

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the proposed device and the predicate devices, K191026 and K130542 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the DeepCatch is substantially equivalent in safety and effectiveness to the predicate device as described herein.