MEDICALIP Co., Ltd
% GeumHyeon Kim
Lead Consultant
DT&S Co., Ltd.
#202, Mario Tower, 28, Digital-ro 30-gil
Guro-gu, 08389
SEOUL KR

November 7, 2019

Re: K191026
Trade/Device Name: Medip Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 5, 2019
Received: September 16, 2019

Dear GeumHyeon 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191026

Device Name
MEDIP PRO

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7F Changkyung Building, 174, Yulgok-ro, Jongno-gu, Seoul, Republic of Korea, 03127

K191026

510(k) Summary

[As Required by 21 CFR 807.92]

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

November 7, 2019

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

- Name of Manufacturer: MEDICAL IP Co., Ltd.
- Address: 7F, Changkyung Building,174, Yulgok-ro, Jongno-gu, Seoul, Republic of Korea, 03127
- Telephone No.: +82-2-2135-9148

3. Submission Correspondent

- Name of company: DT&S Co., Ltd.
- Address: #202, Mario Tower, 28, Digital-ro 30-gil, Guro-gu, Seoul, 08389, Republic of Korea
- Contact Name: GeumHyeon Kim
- Contact Title Lead Consultant
- E-mail Address ghkim@dtncro.co.kr
- Telephone No.: +82-2-357-8401
- Fax No.: +82-2-357-8027

4. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade Name	MEDIP PRO
Regulation Number	21 CFR 892.2050
Regulation Name	Picture archiving and communications system
Regulation Class	II
Product Code	LLZ
Product Code Name	System, Image Processing, Radiological

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

The identified predicate devices within this submission are shown as follow:

Predicate device

- 510(k) Number: K173619
- Applicant: Materialise N.V.
- Classification Name: System, Image processing, Radiological
- Trade Name: Mimics inPrint

Reference device

- 510(k) Number: K161841
- Applicant: 3D Systems, Inc.
- Classification Name: System, Image processing, Radiological
- Trade Name: D2P

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

MEDIP PRO is medial image processing software that provides 3D reconstruction and visualization of ROI, advanced image quality improvement, auto segmentation for specific target, texture analysis and etc. through loading DICOM file imaged from CT or MRI by user(doctors). Also, it supports exporting STL data for 3D printing.

7. Indications for Use [21 CFR 807.92(a)(5)]

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.

8. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences in the technological characteristics of this device compared to the predicate devices which adversely affect safety or effectiveness. The below table is summarized and compared with the technological characteristics between the MEDIP PRO and the predicate device:

Table 1. Technological Characteristics Comparison

	Proposed Device	Predicate Device	Reference Device
K Number	K191026	K173619	K161841
Manufacturer	MEDICALIP.CO.,LTD	Materialise N.V.	3D Systems, Inc.
Model	MEDIP PRO	Mimics inPrint	D2P
Product Code	LLZ	LLZ	LLZ
Indications for Use	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.	Mimics inPrint 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. For this purpose, the Mimics inPrint output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications. Mimics inPrint should be used in conjunction with other diagnostic tools and expert clinical judgement.	The D2P software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative software for surgical planning. 3D printed models generated from the output file are meant for visual, non-diagnostic use.
Type of Use	Prescription Use	Prescription Use	Prescription Use
Component	Stand-alone software	Stand-alone software	Stand-alone software
Image Support Type	DICOM imaging information from CT, MRI	DICOM imaging information from CT, MRI	DICOM imaging information from CT, MRI
Feature/ Functionality	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 Exporting STL data for 3D Printing	Analysis & Measurement Image Enhancement 2D/3D visualization Segmentation 3D Rendering Exporting STL data for 3D Printing

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.

Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Software Validation

The MEDIP PRO contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

- Verification of each independent software subsystem against defined requirements
- Verification of interfaces between software subsystems against defined interface requirements
- Validation of fully integrated system including all subsystems against overall system requirements.

2) Performance Test

The MEDIP PRO 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.

Comparative Performance Test

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

- Measurement of Distance – Phantom study
- Segmentation Performance
- Usability test – System measurements & segmentation

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

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

Based on a comparison of the intended use and technological characteristics, the MEDIP PRO software is substantially equivalent to the identified predicate device and reference device. Minor differences in technological and performance characteristics did not raise new or different questions of safety and effectiveness. Additionally, the non-clinical testing supports that the system performs in accordance with its intended use and is as safe, as effective, and performs as well as the predicate device and reference device.