Medicore Co., Ltd.
℅ DoGyun Lim
Senior Researcher
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro
Seoul, Mapo-gu 03909
REPUBLIC OF KOREA

September 13, 2021

Re: K212412
Trade/Device Name: IRIS-XP
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulatory Class: Class I, reserved
Product Code: LHQ
Dated: July 26, 2021
Received: August 3, 2021

Dear Dogyun Lim:

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

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)*
K212412

Device Name
IRIS-XP

Indications for Use *(Describe)*
The IRIS XP is a thermal based imaging device intended for measuring relative skin temperature generated by the human body in the clinical, hospital, acute care settings, surgery, healthcare practitioner facilities or in any environment where healthcare is provided by a qualified healthcare professional. (for adjunctive use only)
The IRIS XP provides for use with both laptop and desktop computers. The computer provides the user interface, image storage and display. Use of this device is determined by the healthcare professional and is based upon his or her of the patient's medical condition and requirements. The patient populations include all assessment age groups from adult to pediatric and neonatal. The device is for providing thermal images of the human body. This device is intended for use by qualified healthcare personnel who are trained in its use.

The system is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device.

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]

K212412

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

July 26, 2021

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

- Name of Manufacturer: Medicore Co., Ltd.
- Address: No. 801~803, Joonganginnotech, 148, sagimakgolro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of korea [Zip.13207]
- Contact Name: Kyo-Bum, Kim
- Telephone No.: +82-2-2056-2600
- Fax No.: +82-2-412-1948
- Email Address: mcbum@medi-core.co.kr
- Registration No.: 2000010846

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

Trade/Device Name	IRIS-XP
Common Name	Thermography system, infrared
Regulation Number	21 CFR 884.2980
Regulation Name	System, Telethermographic (Adjunctive Use)
Regulation Class	Class I
Product Code	LHQ

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

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

- 510(k) Number: K003332
- Applicant: Meditherm
- Trade/Device Name: Meditherm Med2000
- Regulation Number: 21 CFR 884.2980
- Regulation Name: System, Telethermographic (Adjunctive Use)
- Regulation Class: Class I
- Product Code: LHQ

The predicate device has not been subject to a design-related recall

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

IRIS-XP shows an image analysis on the display to measure the amount of infrared rays radiated from the patient. The appropriate color image according to the temperature difference is shown on the screen. The IRIS XP is intended for relative skin temperature measurements (temperature mapping) for adjunctive use only.

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

The IRIS XP is a thermal based imaging device intended for measuring relative skin temperature generated by the human body in the clinical, hospital, acute care settings, surgery, healthcare practitioner facilities or in any environment where healthcare is provided by a qualified healthcare professional. (for adjunctive use only)

The IRIS XP provides for use with both laptop and desktop computers. The computer provides the user interface, image storage and display. Use of this device is determined by the healthcare professional and is based upon his or her of the patient's medical condition and requirements. The patient populations include all assessment age groups from adult to pediatric and neonatal. The device is for providing thermal images of the human body. This device is intended for use by qualified healthcare personnel who are trained in its use.

The system is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device.

7. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

The indications for use of IRIS-XP is the same as the predicate device.

And the temperature range and measurement accuracy of IRIS-XP are the same as the predicate device.

The IRIS-XP substantially equivalent to legally marketed predicate devices (MEDITHERM MED2000) with respect to indications for use and technology characteristics. The table below presents comparisons for each device:

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

	Proposed Device	**Predicate Device**
Product Name	IRIS-XP	MEDITHERM MED2000
510(k) Number	Not known	K003332
Manufacturer	MEDICORE Co., Ltd.	MEDITHERM, INC
Product Code	LHQ	LHQ
Device Class	I	I
Indications for Use	We update the IFU statement as follow: The IRIS XP is a thermal based imaging device intended for measuring relative skin temperature generated by the human body in the clinical, hospital, acute care settings, surgery, healthcare practitioner facilities or in any environment where healthcare is provided by a qualified healthcare professional. (for adjunctive use only) The IRIS XP provides for use with both laptop and desktop computers. The computer provides the user interface, image storage and display. Use of this device is determined by the healthcare professional and is based upon his or her of the patient's medical condition and requirements. The patient populations include all assessment age groups from adult to pediatric and neonatal. The device is for providing thermal images of the human body. This device is intended for use by qualified healthcare personnel who are trained in its use. The system is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device.	The Meditherm med2000 thermal imaging system is a thermal based imaging device intended for viewing and digitally storing thermal patterns generated by the human body in the clinical, hospital, acute care settings, surgery, healthcare practitioner facilities or in any environment where healthcare is provided by a qualified healthcare professional. The Meditherm med2000 provides for use with both laptop and desktop computers. The computer provides the user interface, image storage and display. Use of this device is determined by the healthcare professional and is based upon his or her of the patient's medical condition and requirements. The patient populations include all assessment age groups from adult to pediatric and neonatal. The device is for providing thermal images of the human body. This device is intended for use by qualified healthcare personnel who are trained in its use.
Intended use environment	Hospital	Hospital
Specifications		
Power source	Line In: 100-120/200-240 VAC, 50/60 Hz Line Out: 100-240VAC, 50/60 Hz	100-240 VAC, 47-63 Hz
AC to DC converter	DC 12V, 3A	5VDC, minimum of 3 Watts continuous, 1 Ampere surge at start-up
Operating Temperature	10℃ to 40℃	18℃ to 30℃
Storage temperature	-20℃ to 60℃	-30℃ to 80℃
Temperature Range	14.5℃ to 40℃	0℃ to 50℃
Relative temperature	< ± 0.8 °C	<±1℃ of indicated temperature in range

	Proposed Device	Predicate Device
Measurement accuracy		20℃ to 40℃
Field of view	50°(H) x 37.5°(V) with wide angle lens	25mm: 11° x 8° 16mm: 17° x 12° 11mm: 25° x 18° 8.5mm: 32° x 24° 5.8mm: 50° x 37°
Focus range	30cm to ∞	25mm: 30cm to ∞ 16mm: 30cm to ∞ 11mm: 30cm to ∞ 8.5mm: 30cm to ∞ 5.8mm: 1m to ∞

The table also provides rationale for a little difference in support of substantial equivalence to the Predicate devices

[Table 2. Little difference with Predicate Device]

Justification to Support Substantial Equivalence
IRIS-XP is hardly different from the MEDITHERM MED2000 except for Operating temperature, storage temperature, measurement accuracy, field of view and focus range. But the above differences are inherent characteristics of device. The most important temperature range is same to predicate device. Therefore, the differences in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Test summary

The IRIS-XP complies with voluntary standards for electrical safety and electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The IRIS-XP complies with the electrical safety and electromagnetic compatibility requirements established by the standards.

- Electrical Basic Safety and Essential Performance requirements in accordance with IEC 60601-1:2005/AM1:2012
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014

2) Software Validation

The IRIS-XP contain 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:

- "The content of premarket submissions for software contained in medical devices, on May 11, 2005"

Clinical Test Summary

Clinical testing was not required to demonstrate the substantial equivalence of the IRIS-XP to its predicate device.

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

The IRIS-XP has similar intended use and technical characteristics to the predicate device. Based on those information, we conclude that the differences between the proposed device and predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness.