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August 7, 2020

BY E-MAIL

Christa Gilder
Meridian Kiosks
312 South Pine Street
Aberdeen, NC 28315

RE: Regulatory Status of Personnel Management Kiosk with Thermal Camera

Dear Christa:

As requested, this letter includes our assessment of the regulatory status of the personnel management kiosk distributed by Meridian Kiosks, which includes a thermal camera. In short, it appears from our review of the information provided that the kiosk satisfies the performance and labeling requirements outlined in FDA's enforcement policy for telethermographic systems for initial temperature assessment for triage use during the COVID-19 public health emergency. Thus, the kiosks can likely be distributed during the public health emergency without prior U.S. Food and Drug Administration (FDA) clearance or approval or compliance with FDA's Quality System Regulation (QSR).

I. Background on Kiosk with Thermal Camera

It is our understanding that Meridian Kiosks imports and distributes a personnel management kiosk that includes a thermal camera. The kiosk is intended to protect the health and safety of employees and guests by screening the body temperature of individuals entering a facility (e.g., a workplace). The kiosk is intended to be used to prevent anyone with an elevated body temperature from entering the facility.

The personnel management kiosk also includes additional functionalities, such as facial recognition features for security screening, but those functionalities are not relevant for the purpose of this letter.

II. Overview of FDA Regulation of Telethermographic Systems

A "device" is defined, in relevant part, in the Federal Food, Drug, and Cosmetic Act (FDC Act) as an "instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, . . . which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man."[1]

Telethermographic systems are regulated by FDA as class II medical devices that, in ordinary circumstances, require the submission to FDA and clearance of a 510(k) premarket notification prior to commercial distribution. A "telethermographic system" is defined as "an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories."[2]

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency due to COVID-19.[3] Pursuant to this emergency declaration, in April 2020, FDA issued an enforcement policy titled "Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."[4] In this enforcement policy, FDA states that telethermographic systems intended for a "medical purpose," are regulated as medical devices. FDA construes "medical purpose" broadly, to include body temperature assessment, even when not in a healthcare environment.[5]

In this enforcement policy, FDA states that it "does not intend to object to the distribution and use of telethermographic systems intended for initial body temperature assessment for triage use" without compliance with the following regulatory requirements that would normally apply: (1) the requirement for submission of a 510(k) premarket notification, (2) requirements related to reports of corrections and removals (21 C.F.R. Part 806), (3) registration and listing requirements (21 C.F.R. Part 807), (4)

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1 FDC Act § 201(h).

2 21 C.F.R. § 884.2980.

3 HHS, Determination that a Public Health Emergency Exist (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

4 FDA, Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Apr. 2020), https://www.fda.gov/media/137079/download.

5 *Id.* at 3.

the QSR (21 C.F.R. Part 820), and (5) Unique Device Identification requirements (21 C.F.R. Part 830 and 21 C.F.R. § 801.20).[6]

In order to qualify for the enforcement policy, to be able to distribute telethermographic systems without a 510(k) clearance or compliance with other regulatory requirements, the telethermographic system must comply with performance and labeling requirements outlined in the enforcement policy.

The enforcement policy is only in effect for the duration of the public health emergency declared by the Secretary of HHS. When the public health emergency is terminated by the Secretary of HHS, a 510(k) premarket notification will be required, and the manufacture, labeling, design, and distribution of the kiosk will need to comply with applicable FDA requirements (e.g., the QSR).

A. Performance Requirements

To comply with the performance requirements[7] in the enforcement policy, the device must be:

1. Tested and labeled consistent with the following standard: IEC 80601-2-59:2017: *Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*; OR

2. Tested using alternative performance specifications that provide similar results to IEC 80601-2-59:2017. This could include:

    a. The laboratory temperature accuracy of a screening telethermographic system, including the measurement uncertainty, is less than or equal to ±0.5°C (±0.9°F) over the temperature range of at least 34-39°C (93.2-102.2°F);

    b. The system includes an accurate blackbody temperature reference source;

    c. Both stability and drift are less than 0.2°C (0.36°F) within a timeframe specified by the manufacturer; and

    d. The device risk assessment addresses all potential safety issues, including: i) Electrical safety; ii) Electromagnetic compatibility; iii) Mechanical

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6 *Id.* at 4.

7 *Id.* at 5.

safety; iv) Excessive temperatures and other hazards; v) Accuracy of controls, instruments, and information display; vi) Considerations for software associated with Programmable Electrical Medical Systems including network connections; and vii) Usability.

B. Labeling Requirements

The enforcement policy includes the following labeling requirements[8]:

1. The labeling must include a prominent notice that the "measurement should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease."

2. The labeling must include a clear statement that:

    a. Elevated body temperature should be confirmed with secondary evaluation methods (e.g., a clinical grade contact thermometer);

    b. Public health officials, through their experience with the device in the particular environment of use, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement;

    c. The technology should be used to measure only one subject's temperature at a time; and

    d. Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.

3. The labeling must include a clear description of:

    a. Device performance specifications and the methodology and frequency of any calibration needed to maintain the labeled specifications;

    b. How to use the thermal image to make a temperature measurement to within the stated device accuracy;

    c. A description and purpose of the blackbody reference source (used for thermal drift compensation) and its importance in obtaining an accurate temperature assessment;

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8 *Id.* at 5.

d. The reference body site used for temperature estimation, including any calibration or correction needed to estimate the temperature at that location, and the accuracy of the measurement at the reference site (e.g., oral, tympanic membrane);

e. How different environmental and system setup factors can affect the measurement, including the body site chosen for measurement, the condition of the screening site (e.g., screening background, ambient temperature and humidity, airflow);

f. Different factors to consider in the design of the facility protocol (e.g., installation, viewing angle, blackbody temperature reference source);

g. The installation procedures and qualification testing that should be performed during installation or when imaging equipment is being relocated; and

h. The appropriate imaging distance based on the spatial resolution and performance of the camera.

4. The labeling must reference and be consistent with the guidelines in ISO/TR 13154: 2017: *Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph*; and

5. The labeling must include a clear identification that the device is not FDA-cleared or approved.

III. Applicability of Enforcement Policy to the Personnel Management Kiosk with Thermal Camera

From our review of the materials provided, it appears that the personnel management kiosk meets the minimum performance requirements outlined in the enforcement policy. As summarized above, the enforcement policy requires testing to IEC 80601-2-59:2017 or to alternative performance specifications that provide similar results to this standard. The thermal camera in the kiosk was not tested to IEC 80601-2-59:2017, but appears to meet the alternative performance requirements outlined in the enforcement policy.

Laboratory temperature accuracy was assessed over a temperature range of 34-39°C, and the measurement uncertainty was confirmed to be less than or equal to ±0.5°C. The system uses the NightinGale blackbody temperature reference source, which is set at

12 inches from the sensor face. The temperature stability and drift were confirmed to be less than 0.2°C in a period of five seconds. The kiosk also conforms to a series of standards assessing electromagnetic compatibility and electrical safety.

Additionally, the kiosk User Manual appears to satisfy all applicable labeling requirements in the enforcement policy. The User Manual includes a statement that the device "should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease or health condition" (item 1). It states that "[e]levated body temperature in the context of use should be confirmed with secondary evaluation methods, such as a non-contact infrared thermometer or clinical grade contact thermometer" (item 2.a). It states that "[p]ublic health officials, through their experience with the device in the particular environment of use, should determine the significance of any fever or elevated temperature based on the temperature readings of the device" (item 2.b). The instructions for use address all topics in items 2.b and 3. Item 2.d, which requires a statement that "visible thermal patterns are only intended for locating the points from which to extract the thermal measurement," is not addressed in the User Manual because it is not applicable to the kiosk device. Finally, the User Manual references ISO/TR 13154: 2017 (item 4) and includes a statement that the device is not FDA-cleared or approved (item 5).

* * *

In summary, based on our review of the information provided, the kiosk appears to satisfy all performance and labeling requirements under FDA's enforcement policy for telethermographic systems, and therefore can likely be distributed during the public health emergency without prior U.S. Food and Drug Administration (FDA) clearance or approval or compliance with FDA's Quality System Regulation (QSR).

Sincerely,

/s/ Dara Katcher Levy

Dara Katcher Levy