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INTERNATIONAL BUSINESS ALERT

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What to know for importation and marketing of thermometers under FDA's relaxed standard during COVID-19

Clinical electronic thermometers, including any contact and non-contact clinical electronic thermometers, are regulated as Class II devices under the 21 CFR 880.2910, product code FLL. Under normal circumstances, manufacturers of clinical electronic thermometers are required to submit a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to the U.S. Food and Drug Administration (FDA) and to receive FDA clearance prior to marketing these devices in the United States.

On April 4, 2020, the FDA issued the Guidance for Industry and Food and Drug Administration Staff: Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, which permits the importation of clinical electronic thermometers during the COVID-19 pandemic without FDA 510(k) preclearance.

Under this policy, "to help ensure the availability of equipment that might offer some benefit to health care providers and the general public during the public health emergency," the FDA will not object to the distribution and use of clinical electronic thermometers that are not currently 510(k) cleared unless undue risks are involved. Therefore, clinical electronic thermometers are permitted without obtaining the FDA 510(k) clearance and the FDA presumes no undue risks exist so long as the device meets the following four requirements:

1. The device is manufactured consistent with 21 CFR Part 820, ISO 13485:2016 *Medical devices – Quality management systems*

Information about COVID-19 and its impact on local, state and federal levels is changing rapidly. This article may not reflect updates to news, executive orders, legislation and regulations made after its publication date. Visit our COVID-19 resource page to find the most current information.

– *Requirements for regulatory purposes*, or equivalent quality system approach.

2. The device has marketing authorization in another regulatory jurisdiction (European CE Mark, Australian Register of Therapeutic Goods Certificate of Inclusion, Health Canada License, or Ninsho certification in Japan), or the performance of the device conforms to various standards listed in the FDA COVID-19 Enforcement Policy.

3. The device labeling includes a clear description of the available data on the device's indications or functions including:

    a. Device performance;

    b. Method of determining temperature;

    c. Potential risks; and

    d. Cleaning and reprocessing instructions.

4. The device labeling includes a clear identification that the device is not FDA approved or cleared.

This FDA special COVID-19 enforcement policy enables importation of thermometers from overseas to the U.S. to satisfy increasing domestic demand. However, the FDA does not confirm the authenticity or quality of thermometers imported from overseas. Importers must therefore perform proper due diligence and take appropriate steps to verify the authenticity and quality of the products prior to the import. In addition, the FDA provided no guidance on whether taking temperatures is sufficient to prescreen for COVID-19, and companies should follow the CDC and other federal and state guidelines on prescreening their employees or customers.

This FDA special COVID-19 Enforcement Policy will remain in effect for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services and through any renewals. Following the public emergency, importers must continue to follow the FDA Guideline on the Content of Premarket Notification [510(k)] Submission for Clinical Electronic Thermometers and other FDA regulations, and obtain 510(k) preclearance prior to import in order to market clinical electronic thermometers in the United States.

For more information please contact Yuanyou Yang or any member of Porter Wright's International Business & Trade Practice Group.