

Dahua Thermal Solutions, Medical Devices & the FDA

07/01/2020

Dahua offers the Thermal Temperature Monitoring Solution and the Thermal Temperature Station to detect elevated body temperature, one of many possible symptoms associated with COVID-19. Dahua's customers are using our thermal solutions to identify elevated body temperature among patrons, employees and other visitors to their premises in an effort to help reduce the spread of COVID-19.

A question we sometimes receive is whether the Dahua thermal solutions are medical devices subject to regulation and oversight by the U.S. Food and Drug Administration (FDA). In April 2020, the FDA issued guidance (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health>) indicating that the FDA regards telethermographic systems intended for adjunctive diagnostic screening to be "medical devices" requiring 510(k) clearance prior to marketing for sale in the United States. Dahua thermal solutions may be, and commonly are, used by our customers for adjunctive diagnostic screening, and as such, qualify as "medical devices" as set out in the FDA guidance.

In that same guidance, the FDA waived the 510(k) clearance requirement during the pendency of the COVID-19 public health emergency where such devices do not create an undue risk. The FDA believes telethermographic systems will not create an undue risk when certain standards related to the performance of the system and the transparency and clarity of information in the product labeling are present. Dahua is currently marketing and selling its thermal solutions in the United States without 510(k) clearance in reliance upon the FDA guidance.

Dahua intends to submit applications for 510(k) clearance for our thermal solutions to enable the continued marketing and sale of the Dahua thermal solutions in the United States for adjunctive diagnostic screening when the current public health emergency ends. We note that there is no guarantee that an application will be approved or on what timeframe.

Disclaimer: As discussed above, the Dahua thermal solutions are not FDA-cleared or approved. The solutions should not be solely or primarily used to diagnose or exclude a diagnosis of COVID-19 or any other disease. Elevated body temperature should be confirmed with secondary evaluation methods (e.g., an NCIT or clinical grade contact thermometer). Users, through their experience with the solutions in the particular environment of use, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement. Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.

Dahua Technology USA Inc.