Press Releases

EXERGEN: FDA POSTS DRAFT TRANSITION PLAN FOR MEDICAL DEVICES THAT FALL WITHIN ENFORCEMENT POLICIES ISSUED DURING THE COVID 19 PUBLIC HEALTH EMERGENCY

Exergen calls on FDA to recall and prevent future sale of non-contact infrared thermometers whose inaccuracy is a danger to the public health

WATERTOWN, Mass., April 12, 2022 /PRNewswire/ -- The Food and Drug Administration (FDA) has given public access to its draft guidance entitled "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency"[1]. The FDA has now made comments to its guidelines public.

Exergen Corporation has submitted comments regarding the inaccuracy of non-contact infrared thermometers (NCITs).[2] This continues the company's mission of helping to protect public health by providing only medically accurate thermometers for retail sale as opposed to NCITs, the accuracy of which have been called into serious question by a recent study report co-authored by several FDA scientists[3].

As Exergen notes in its comments, the highly controlled study conducted in November 2021 found that clinical bias and uncertainty for all tested NCIT models exceeded the stated accuracy in their product labeling, *with up to 88% of the individual temperature measurements outside of the labeled accuracy stated by the* manufacturers. Study authors concluded: "Model-to-model variability and individual model accuracy in the displayed temperature are a major source of concern. Users should be aware of the consequences of false negatives and false positives when using NCITs as a screening tool."

Based on this study and many others cited in Exergen's comments to the FDA regarding the ineffectiveness of NCITs, Exergen requests that the FDA take the following actions:

- Recall all NCIT's as quickly as possible, as such devices are not effective as consistently demonstrated by numerous studies and the complete lack of any studies supporting any NCIT's accuracy;
- Issue a Public Notice strongly recommending that NCITs not be used under any circumstances for screening or detecting persons with fever who may have Covid-19 or any other disease;
- Rescind the April 2020 Enforcement Policies that allows NCITs to be marketed without 510(k) authorization;
- Increase the scrutiny of any new 510(k) notifications for NCITs to be certain that they can reliably measure clinically accurate and medically relevant temperature, and that the labeling properly notes the limitations on that use.

"Now is the time for the FDA to remove non-contact thermometers from the market until they are certain they can reliably measure clinically accurate and medically relevant temperature in order to protect public health," said Francesco Pompei, Ph.D., CEO of Exergen Corporation. "The study report co-authored by FDA scientists supports what we've known all along: NCITs are utterly ineffective in measuring temperature. It is unconscionable to keep them on the market because of their threat to public health."

ABOUT EXERGEN CORPORATION

Exergen manufactures and markets two series of the TemporalScanner thermometer: a professional version for hospitals and clinics, and a consumer version sold in major retailers nationwide. More than two billion temperatures are taken each year with TemporalScanners. Used in thousands of hospitals and clinics across the country as well as in millions of homes, TemporalScanners are the #1 preference of pediatricians, nurses, and mothers. The Exergen TemporalScanner's accuracy is supported by more than 100 peer-reviewed published clinical studies covering all ages from preterm infants to geriatrics and all care areas from hospitals to homes. For additional information, visit www.exergen.com.

[1] U.S. Food and Drug Administration. Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. Regulations.gov. 2021 December 23. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease

[2] https://www.regulations.gov/comment/FDA-2021-D-1118-0022

[3] Sullivan, S.J.L., Rinaldi, J.E., Hariharan, P. *et al.* Clinical evaluation of non-contact infrared thermometers. *Sci Rep* 11, 22079 (2021). https://doi.org/10.1038/s41598-021-99300-1

SOURCE Exergen

For further information: Sarah Ciuba, Rosica Communications, sarah@rosica.com, 201.843.5600