FDA 510(k) Premarket Notification

K213650 ThermPix Thermovisual Camera

CLEARED

Apr 12, 2022
144 days to decision

K213650 · Product code: **LHQ** · Radiology
Source: https://www.510kdatabase.net/k213650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Telethermographic (adjunctive Use) (LHQ)
Date received	Nov 19, 2021
Decision date	Apr 12, 2022
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Usa Therm, Inc.**
Location	Aventura, FL, US
Contact	Ariel Soffer
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy**
Contact	Mary Vater

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov