FDA 510(k) Premarket Notification

CLEARED

K200999 Thermidas IR System (ThIR-A615)

Jan 6, 2021
265 days to decision

K200999 · Product code: **LHQ** · Radiology
Source: https://www.510kdatabase.net/k200999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Telethermographic (adjunctive Use) (LHQ)
Date received	Apr 16, 2020
Decision date	Jan 6, 2021
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Thermidas Americas, Inc.**
Location	South Pasadena, FL, US
Contact	Karo Kujanpaa
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Gunster, Yoakley & Stewart, P.A.**
Contact	Samantha L Prokop

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