

**K200999 Thermidas IR System (ThIR-A615)**Jan 6, 2021  
265 days to decisionK200999 · Product code: **LHQ** · Radiology  
Source: <https://www.510kdatabase.net/k200999/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Gunster, Yoakley &amp; Stewart, P.A.</b>
Contact	Samantha L Prokop

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200999/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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