

K240447 ThermoChem HT-2000 System and Intraperitoneal Hyperthermia (IPH) Procedure Kit (HT-2000)

May 5, 2025
445 days to decision

K240447 · Product code: **MLW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k240447/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Warmer, Peritoneal Dialysate (MLW)
Date received	Feb 15, 2024
Decision date	May 5, 2025
Days to decision	445 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thermasolutions, LLC
Location	White Bear Lake, MN, US
Contact	Rhea Johny
510(k) history	2 submissions · 1 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	DuVal & Associates, P.A.
Contact	Jessica Czamanski

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

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Device record: <https://www.510kdatabase.net/k240447/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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