

K252947 HistoSonics® Planning ToolMay 29, 2026
256 days to decisionK252947 · Product code: **QTZ** · Radiology
Source: <https://www.510kdatabase.net/k252947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Ablation Therapy Planning And Evaluation (QTZ)
Date received	Sep 15, 2025
Decision date	May 29, 2026
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	HistoSonics, Inc.
Location	Plymouth, MN, US
Contact	LeeAnne Swiridow
510(k) history	4 submissions · 3 cleared · 2023-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252947/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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