

K233466 Edison SystemMar 13, 2024
141 days to decisionK233466 · Product code: **QGM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233466/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound System For Non-thermal, Mechanical Tissue Ablation (QGM)
Date received	Oct 24, 2023
Decision date	Mar 13, 2024
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	HistoSonics, Inc.
Location	Plymouth, MN, US
Contact	Daniel Kosednar
510(k) history	3 submissions · 2 cleared · 2023-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233466/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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