FDA 510(k) Premarket Notification

K241902 Edison System

CLEARED

Oct 30, 2024
121 days to decision

K241902 · Product code: **QGM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound System For Non-thermal, Mechanical Tissue Ablation (QGM)
Date received	Jul 1, 2024
Decision date	Oct 30, 2024
Days to decision	121 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	3 submissions · 2 cleared · 2023-2024