

K200061 HEATfx Microwave Ablation System, HEATfx Microwave Ablation System Cart, HEATfx 2.1 Needle, HEATfx 2.1 S Needle, Multi-Point Thermal Sensor (MTS)Jul 9, 2020
178 days to decisionK200061 · Product code: **NEY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k200061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Jan 13, 2020
Decision date	Jul 9, 2020
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Galil Medical, Inc.
Location	Lake Jackson, TX, US
Contact	Amy Mckinney
510(k) history	8 submissions · 8 cleared · 2011-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026