

K181153 ICEfx Cryoablation SystemMay 15, 2018
14 days to decisionK181153 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 1, 2018
Decision date	May 15, 2018
Days to decision	14 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	Rachel Owens
510(k) history	8 submissions · 8 cleared · 2011-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181153/> 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