

K152133 IcePearl 2.1 CX Cryoablation Needle, IcePearl 2.1 CX Prostate Cryoablation Kit Visual-ICE System, IceFORCE 2.1 CX Cryoablation Needle, IceFORCE 2.1 CX Prostate Cryoablation Kit Visual-ICE SystemAug 28, 2015
28 days to decisionK152133 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k152133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jul 31, 2015
Decision date	Aug 28, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Galil Medical , Ltd.
Location	Washington, Dc, DC, US
Contact	LYNNE DAVIES
510(k) history	23 submissions · 23 cleared · 1998-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152133/> 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 May 30, 2026