

**K181741 IceSphere 1.5 CX Cryoablation Needle**Jul 30, 2018  
28 days to decisionK181741 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181741/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jul 2, 2018
Decision date	Jul 30, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Galil Medical , Ltd.</b>
Location	Washington, Dc, DC, US
Contact	Stacey Backlund
510(k) history	23 submissions · 23 cleared · 1998-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181741/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026