

**K183213 IceSense 3, ProSense, MultiSense**Dec 20, 2019  
396 days to decisionK183213 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183213/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Nov 19, 2018
Decision date	Dec 20, 2019
Days to decision	396 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>IceCure Medical , Ltd.</b>
Location	Caesarea, IL
Contact	Elisabeth Sadka
510(k) history	4 submissions · 4 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183213/> 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 25, 2026