

K260377 XSense Cryoablation System with CryoProbesFeb 24, 2026
19 days to decisionK260377 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k260377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Feb 5, 2026
Decision date	Feb 24, 2026
Days to decision	19 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	IceCure Medical , Ltd.
Location	Caesarea, IL
Contact	Maayan Levi
510(k) history	4 submissions · 4 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260377/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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