

**K251928 CoolCryo - Cryoapplicator for cardiac cryoablation  
(CC01-01)**Feb 13, 2026  
235 days to decisionK251928 · Product code: **GEH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k251928/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jun 23, 2025
Decision date	Feb 13, 2026
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir (CC01-21)

**APPLICANT**

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Company	<b>Medinice S.A.</b>
Location	Warsaw, PL
Contact	Sanjeev Choudhary
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>MEDlcept</b>
Contact	Melissa DeHass

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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