

**K102360 ICESENCE 3**Nov 29, 2010  
102 days to decisionK102360 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k102360/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Unit, Cryosurgical, Accessories (GEH) |
| Date received         | Aug 19, 2010                          |
| Decision date         | Nov 29, 2010                          |
| Days to decision      | 102 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/k102360/> 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