

**K253230 ERBECRYO 2 Cryosurgical Unit and Accessories:  
ERBECRYO 2 cryosurgical unit**Apr 22, 2026  
205 days to decisionK253230 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253230/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 29, 2025
Decision date	Apr 22, 2026
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Erbe Flexible Cryoprobe

**APPLICANT**

---

Company	<b>Erbe Elektromedizin GmbH</b>
Location	Orange, CA, US
Contact	Matthias Kolle
510(k) history	15 submissions · 15 cleared · 1994-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253230/>. 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 13, 2026