

K201260 Dermal Cooling SystemSep 24, 2020
136 days to decisionK201260 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 11, 2020
Decision date	Sep 24, 2020
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	R2 Technologies, Inc.
Location	San Ramon, CA, US
Contact	Ragan Reppond
510(k) history	3 submissions · 3 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201260/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026