

K161480 R2 Dermal Cooling SystemOct 5, 2016
127 days to decisionK161480 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 31, 2016
Decision date	Oct 5, 2016
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	R2 Dermatology
Location	San Ramon, CA, US
Contact	Kristine Tatsutani
510(k) history	1 submissions · 1 cleared · 2016-2016

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