

K171398 Dermal Cooling SystemJul 6, 2017
55 days to decisionK171398 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k171398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 12, 2017
Decision date	Jul 6, 2017
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	R2 Dermatology ,Inc
Location	San Ramon, CA, US
Contact	Kristine Tatsutani
510(k) history	1 submissions · 1 cleared · 2017-2017

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