

K161296 Cool RenewalJul 6, 2016
58 days to decisionK161296 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 9, 2016
Decision date	Jul 6, 2016
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cool Renewal, LLC
Location	Nashville, TN, US
Contact	ASHLEY RAINS
510(k) history	1 submissions · 1 cleared · 2016-2016

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