

K211526 Portable Scalp Cooling SystemOct 21, 2021
157 days to decisionK211526 · Product code: **PMC** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scalp Cooling System (PMC)
Date received	May 17, 2021
Decision date	Oct 21, 2021
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cooler Heads Care, Inc.
Location	San Diego, CA, US
Contact	Kate Dilligan
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies
Contact	Pierre Bounaud

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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