

K213294 Dermal Cooling SystemNov 10, 2022
405 days to decisionK213294 · Product code: **QPZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Contact Cooling For Skin Lesion Pain Relief (QPZ)
Date received	Oct 1, 2021
Decision date	Nov 10, 2022
Days to decision	405 days
Third-party review	No
Combination product	No
PCCP authorized	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

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