

K212331 BodySculpNov 9, 2021
105 days to decisionK212331 · Product code: **PKT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser For Disruption Of Adipocyte Cells For Aesthetic Use (PKT)
Date received	Jul 27, 2021
Decision date	Nov 9, 2021
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rohrer Aesthetics, LLC
Location	Birmingham, AL, US
Contact	Mark Rohrer
510(k) history	6 submissions · 6 cleared · 2018-2024

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