

K160259 ZELTIQ CoolSculpting SystemMar 23, 2016
51 days to decisionK160259 · Product code: **OOK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dermal Cooling Pack/vacuum/massager (OOK)
Date received	Feb 1, 2016
Decision date	Mar 23, 2016
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zeltiq Aesthetics, Inc.
Location	Pleasanton, CA, US
Contact	SHRUTI JAYAKUMAR
510(k) history	13 submissions · 13 cleared · 2012-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160259/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026