

K171992 SculpSureSep 26, 2017
85 days to decisionK171992 · Product code: **PKT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k171992/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser For Disruption Of Adipocyte Cells For Aesthetic Use (PKT)
Date received	Jul 3, 2017
Decision date	Sep 26, 2017
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cynosure, Inc.
Location	Bedford, MA, US
Contact	Amy Tannenbaum
510(k) history	98 submissions · 98 cleared · 1992-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171992/> 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 June 18, 2026