FDA 510(k) Premarket Notification

K171992 SculpSure

CLEARED

Sep 26, 2017
85 days to decision

K171992 · Product code: **PKT** · General & Plastic Surgery
Source: 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