FDA 510(k) Premarket Notification

K162512 truSculpt

CLEARED

Dec 9, 2016
92 days to decision

K162512 · Product code: **PBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Sep 8, 2016
Decision date	Dec 9, 2016
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cutera, Inc.**
Location	Brisbane, CA, US
Contact	BRADLEY RENTON
Website	http://www.cutera.com/
510(k) history	31 submissions · 31 cleared · 2004-2025

Cutera, Inc. is a medical device manufacturer specializing in aesthetic and surgical laser systems. The company operates with a manufacturing facility in Brisbane, US, and maintains a global presence across North America, Europe, and Australia. Cutera has established a strong regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The vast majority of its submissions focus on General & Plastic Surgery devices, reflecting the company's core expertise in this category. The most recent cle...