

K180709 truSculpt RF DeviceJun 6, 2018
79 days to decisionK180709 · Product code: **PBX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k180709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Mar 19, 2018
Decision date	Jun 6, 2018
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary
Other names	truSculpt; truSculpt 3D

APPLICANT

Company	Cutera, Inc.
Location	Brisbane, CA, US
Contact	Brad 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...