

K122389 TRUSCULPTNov 2, 2012
87 days to decisionK122389 · Product code: **PBX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k122389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Aug 7, 2012
Decision date	Nov 2, 2012
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cutera, Inc.
Location	Brisbane, CA, US
Contact	Connie Hoy
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...
