

**K221407 truSculpt iD**Jul 13, 2022  
58 days to decisionK221407 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221407/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 16, 2022
Decision date	Jul 13, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cutera, Inc.</b>
Location	Brisbane, CA, US
Contact	Amogh Kothare
Website	<a href="http://www.cutera.com/">http://www.cutera.com/</a>
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...