

**K112669 TATTOOSTAR EFFECT Y**May 11, 2012  
240 days to decisionK112669 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k112669/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 14, 2011
Decision date	May 11, 2012
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Asclepion Laser Technologies GmbH</b>
Location	Chelmsford, MA, US
Contact	ANTJE KATZER
Website	<a href="https://www.asclepion.com">https://www.asclepion.com</a>
510(k) history	29 submissions · 29 cleared · 2004-2026

Asclepion Laser Technologies GmbH is a leader in medical laser technology for aesthetic medicine and surgery. The company has operated since 1977 and serves customers in more than 70 countries. Asclepion maintains a manufacturing facility in Chelmsford, US, and specializes in innovative laser systems for dermatological and surgical applications. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. 93% of submissions focus on General & Plastic Surgery devices, reflecting the company's core expertise in this category. ...

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