

**K042968 MCL 30 DERMABLATE ER:YAG LASER SYSTEM**Nov 24, 2004  
27 days to decisionK042968 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k042968/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 28, 2004
Decision date	Nov 24, 2004
Days to decision	27 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	GEORGE CHO
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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