

K113489 ORIONJul 27, 2012
247 days to decisionK113489 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k113489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 23, 2011
Decision date	Jul 27, 2012
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Asclepion Laser Technologies GmbH
Location	Chelmsford, MA, US
Contact	ANTJE KATZER
Website	https://www.asclepion.com
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. ...
