FDA 510(k) Premarket Notification

K050900 MEDIOSTAR XT

CLEARED

May 16, 2005
35 days to decision

K050900 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k050900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 11, 2005
Decision date	May 16, 2005
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Asclepion Laser Technologies GmbH**
Location	Chelmsford, MA, US
Contact	REINHARD THIEME
510(k) history	29 submissions · 29 cleared · 2004-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k050900/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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