FDA 510(k) Premarket Notification

K060459 QUADROSTAR 980

CLEARED

Mar 20, 2006
26 days to decision

K060459 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k060459/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 22, 2006
Decision date	Mar 20, 2006
Days to decision	26 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