FDA 510(k) Premarket Notification

K990043 SMOOTHLASE ALEXANDRITE LASER SYSTEM

CLEARED

Feb 11, 1999
36 days to decision

K990043 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k990043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 6, 1999
Decision date	Feb 11, 1999
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Leisegang Medical, Inc.**
Location	Miami, FL, US
Contact	LORNA K LINVILLE
510(k) history	10 submissions · 10 cleared · 1986-1999