FDA 510(k) Premarket Notification

K053628 LIGHTSHEER DUET LASER SYSTEM

CLEARED

Apr 7, 2006
99 days to decision

K053628 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k053628/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 29, 2005
Decision date	Apr 7, 2006
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lumenis, Inc.**
Location	Mchenry, IL, US
Contact	Connie Hoy
510(k) history	43 submissions · 43 cleared · 1979-2022