FDA 510(k) Premarket Notification

K082809 ACUPULSE 30 AND 40 CARBON DIOXIDE LASER SYSTEM

CLEARED

Dec 18, 2008
85 days to decision

K082809 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k082809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 24, 2008
Decision date	Dec 18, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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