FDA 510(k) Premarket Notification

K013864 MODIFICATION TO EPI-STAR SURGICAL LASER SYSTEM, M0DEL DS-60

CLEARED

Feb 8, 2002
79 days to decision

K013864 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k013864/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 21, 2001
Decision date	Feb 8, 2002
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nidek, Inc.**
Location	Mchenry, IL, US
Contact	CAROL PATTERSON
510(k) history	77 submissions · 77 cleared · 1983-2005

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k013864/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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