FDA 510(k) Premarket Notification

K001322 PERFORMER 30 HPS

CLEARED

Jun 30, 2000
65 days to decision

K001322 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k001322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 26, 2000
Decision date	Jun 30, 2000
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cornelia Damsky, Inc.**
Location	Stamford, CT, US
Contact	CORNELIA DAMSKY
510(k) history	4 submissions · 4 cleared · 1985-2000