FDA 510(k) Premarket Notification

K101601 AFFIRM DO DIODE LASER

CLEARED

Sep 23, 2010
107 days to decision

K101601 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k101601/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 8, 2010
Decision date	Sep 23, 2010
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cynosure, Inc.**
Location	Bedford, MA, US
Contact	ANTHONY BURNS
510(k) history	98 submissions · 98 cleared · 1992-2019