FDA 510(k) Premarket Notification

K112324 CERALAS 980NM DIODE LASER FAMILY

CLEARED

Sep 6, 2011
25 days to decision

K112324 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k112324/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 12, 2011
Decision date	Sep 6, 2011
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biolitec Medical Devices, Inc.**
Location	Grandville, MA, US
Contact	HARRY HAYES
510(k) history	9 submissions · 9 cleared · 2011-2012