FDA 510(k) Premarket Notification

K013193 MEGA BEAM/CERALAS NONSTERILE COLLIMATING HANDPIECE

CLEARED

Dec 21, 2001
88 days to decision

K013193 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k013193/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 24, 2001
Decision date	Dec 21, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biolitec, Inc.**
Location	East Longmeadow, MA, US
Contact	CAROL J MORELLO
510(k) history	28 submissions · 28 cleared · 2001-2012