FDA 510(k) Premarket Notification

K030700 CERALAS D 10-60 810NM LASER SYSTEM WITH ENDO LASER VEIN SYSTEM KIT

CLEARED

Jun 4, 2003
90 days to decision

K030700 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k030700/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 6, 2003
Decision date	Jun 4, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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