FDA 510(k) Premarket Notification

K101712 ENDOVASCULAR LAER VEIN SYSTEM KIT

CLEARED

Oct 27, 2010
131 days to decision

K101712 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k101712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 18, 2010
Decision date	Oct 27, 2010
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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