FDA 510(k) Premarket Notification

K102755 CERALAS E/ 1470NM FIBER-COUPLED DIODE LASER FAMILY

CLEARED

Dec 16, 2010
84 days to decision

K102755 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k102755/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 23, 2010
Decision date	Dec 16, 2010
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary
Other names	CREALAS HPD MULTIWAVELENGHT 980NM/ 1470NM FIBER-COUPLED DIODE LASER

APPLICANT

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