

K100726 CERALAS D/ 980NM FIBER-COUPLED DIODE LASER FAMILY, CERALAS E/ 980NM FIBER-COUPLED DIODE LASER FAMILY, CERALAS HPD/ 980NMSep 15, 2010
184 days to decisionK100726 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k100726/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 15, 2010
Decision date	Sep 15, 2010
Days to decision	184 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

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