

**K082263 CERALAS E 980NM DIODE LASER, MODELS E15/980  
AND E30/980**Oct 24, 2008  
77 days to decisionK082263 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k082263/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 8, 2008
Decision date	Oct 24, 2008
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082263/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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