

**K010804 MEGABEAM/CERALAS REUSEABLE HANDPIECE  
AND DISPOSABLE TIPS**Oct 4, 2001  
202 days to decisionK010804 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k010804/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 16, 2001
Decision date	Oct 4, 2001
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biolitec, Inc.</b>
Location	East Longmeadow, MA, US
Contact	CAROL J MORELLO
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/k010804/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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