

**K963340 MEDLITE ND:YAG LASER SYSTEM: NEW DYE  
ACCESSORY HANDPIECE**

May 12, 1997  
259 days to decision

K963340 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k963340/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 26, 1996
Decision date	May 12, 1997
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Continuum Biomedical, Inc.</b>
Location	Mountain View, CA, US
Contact	LAURIE A RIDENER
510(k) history	19 submissions · 19 cleared · 1992-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k963340/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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