

**K013365 PROLITE PULSED LIGHT SYSTEM FOR THE TREATMENT OF PIGMENTED LESIONS AND THE REMOVAL OF TATTOOS**Jan 8, 2002  
90 days to decisionK013365 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k013365/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 10, 2001
Decision date	Jan 8, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medical Bio Care Sweden AB</b>
Location	Albuquerque,, NM, US
Contact	CONNIE W HOY
510(k) history	10 submissions · 10 cleared · 2000-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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