

**K003715 COOLTOUCH ND:YAG LASER SYSTEM, COOLTOUCH-II ND:YAG LASER SYSTEM, MODEL COOLTOUCH, COOLTOUCH II**Mar 1, 2001  
90 days to decisionK003715 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k003715/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 1, 2000
Decision date	Mar 1, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cooltouch Corp.</b>
Location	Roseville, CA, US
Contact	DONALD V JOHNSON
510(k) history	4 submissions · 4 cleared · 2000-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003715/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 3, 2026