

**K131894 NIDEK GREEN LASER PHOTOCOAGULTOR MODEL  
GYC-1000 CONNECTED WITH THE  
ENDOPHOTOCOAGULATION DELIVERY UNIT**Oct 31, 2013  
128 days to decisionK131894 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k131894/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 25, 2013
Decision date	Oct 31, 2013
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Nidek Co., Ltd.</b>
Location	Lake Forest, CA, US
Contact	YONEJI MIZUNO
510(k) history	20 submissions · 19 cleared · 2001-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131894/> 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 June 8, 2026