

**K192045 Ophthalmic Yag Laser System YC-200**Nov 15, 2019  
107 days to decisionK192045 · Product code: **HQF** · Ophthalmic  
Source: <https://www.510kdatabase.net/k192045/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Jul 31, 2019
Decision date	Nov 15, 2019
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192045/> 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 May 14, 2026