

K080513 QLASER SYSTEMJan 30, 2009
340 days to decisionK080513 · Product code: **NHN** · Physical MedicineSource: <https://www.510kdatabase.net/k080513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Laser Non-thermal Instrument With Non-heating Effect For Adjunctive Use In Pain Therapy (NHN)
Date received	Feb 25, 2008
Decision date	Jan 30, 2009
Days to decision	340 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	2035, Inc.
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080513/> Data sourced from FDA 510(k) public records (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. - Generated June 23, 2026