

K212189 FibroLuxSep 2, 2022
416 days to decisionK212189 · Product code: **NHN** · Physical Medicine
Source: <https://www.510kdatabase.net/k212189/>**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	Jul 13, 2021
Decision date	Sep 2, 2022
Days to decision	416 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Multi Radiance Medical
Location	Solon, OH, US
Contact	Andrey Godes
510(k) history	2 submissions · 2 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Insight, Inc.
Contact	Kevin Walls

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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