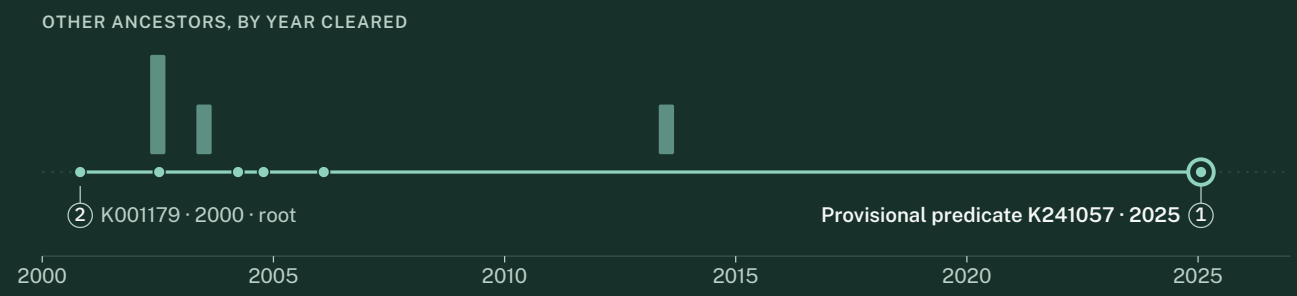
510(k) Report

510(K) PATHWAY ANALYSIS · DEMONSTRATION

Handheld Pain Relief Laser

New handheld prescription laser device using 660 nm and 808 nm diodes for clinician-administered adjunctive temporary relief of minor chronic musculoskeletal neck and shoulder pain.



The family tree of the provisional predicate, K241057: 5 generations of FDA clearances, each citing the one before.

THE REQUEST

We would like a 510(k) pathway report before filing for our handheld, prescription-only laser device. We designed it for adjunctive temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, administered by doctors, nurses, and physical therapists. It uses a 660 nm red laser diode and an 808 nm infrared laser diode, each delivering 100 mW through optical fibers, with output controlled by electrical current. Only the polycarbonate spacer touches the patient's skin; it maintains a safe distance between the device tip and skin. Sessions run from 1 to 8 minutes, with instructions allowing three consecutive 8-minute sessions for 24 minutes total. Our system includes a handpiece, holder…

PREPARED FOR

Demonstration. We wrote this request from the public record of a real device.

RECORDS AS OF

July 22, 2025, the day FDA received that device's 510(k). Nothing later is used.

WHAT REALLY HAPPENED

The last page compares this report with FDA's decision.

The short answer

Plan for a 510(k) under NHN and use K241057 as your provisional predicate. Its handheld red/infrared design and neck/shoulder pain indication fit best. Confirm non-heating performance and support your higher per-diode output, fiber delivery, skin-contact spacer and longer permitted exposure before committing.

PRODUCT CODE	PREMARKET REVIEW	PROVISIONAL PREDICATE	MEDIAN REVIEW
NHN	**510(k)**	**K241057**	**114 days**
Powered Light Based Laser Non-Thermal Instrument With Non-Heating Effect For Adjunctive Use In Pain Therapy. Class II, 21 CFR 890.5500	A 510(k) is required under NHN	Enhanced Handheld Pain Relief Laser, Wuhan Guangdun Technology Co.,Ltd.., 2025	Half took 85–217. 28 of 271 ran past 300

DO THESE FIRST

1. **Finalize intended use and treatment design.** Set patient ages and exclusions, professional use setting, treatment placement, frequency, course, emission mode…
2. **Confirm non-heating performance and NHN classification.** Define treatment-plane output, tolerances, beam geometry and spacer distance; measure dose and temperature under…
3. **Build the K241057 comparison and testing plan.** Explain each output, delivery, contact and dosing difference, and obtain additional technical records where…
4. **Resolve key questions through a Pre-Submission.** Seek FDA feedback on classification, the proposed predicate, comparative testing and the need for…

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1 Your device, as we read it

Everything below is built on this reading of your request. If any of it is wrong, tell us and we rerun the report.

Intended use	Adjunctive temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.
Patients	Patients with minor chronic neck and shoulder pain of musculoskeletal origin; age range not stated.
Users	Doctors, nurses, and physical therapists.
Setting	Not stated.
Body contact	Neck and shoulder; only the polycarbonate spacer contacts the patient's skin.
Sold	By prescription
Technology	Handheld laser device with a 660 nm red laser diode and an 808 nm infrared laser diode. Each diode delivers 100 mW through optical fibers; output is controlled by electrical current. A polycarbonate spacer maintains separation between the device tip and skin and is the only patient-contacting component. Sessions last 1–8 minutes; instructions permit three consecutive 8-minute sessions totaling 24 minutes. System includes a handpiece, holder, charging cable, spacers, safety glasses, eye protection, and carrying case. Not a new version of a device the founder already sells.
Not claimed	No intended-use claims beyond adjunctive temporary relief of minor chronic musculoskeletal neck and shoulder pain are stated.

What we need from you

Your description leaves these open. Each one can change the comparison in section 4, so settle them before you commit to a predicate.

- Intended patient age range and relevant patient exclusions.
- Intended use setting.
- Whether the handpiece and spacers are reusable or single-use; applicable cleaning, disinfection, or disposal instructions.
- Whether the diodes operate simultaneously or sequentially, and whether emission is continuous or pulsed.
- Whether 100 mW per diode is measured at the source, fiber output, or treatment plane, and applicable output tolerances.
- Beam geometry, spot size, treatment area, irradiance, delivered energy, and fluence at the skin.
- Spacer dimensions and actual tip-to-skin distance.
- Treatment placement or movement technique, number of treatment sites, treatment frequency, and overall treatment course.

2 Classification and pathway

FDA requires a 510(k) for NHN, so a cleared predicate is your route to market.

A 510(k) is required under NHN. NHN's current rule requires a 510(k). Section 890.5500 exempts infrared therapeutic heating lamps, not NHN's non-heating pain-therapy type. Keep NHN provisionally, but confirm the non-heating effect with treatment-plane dosimetry and thermal testing; output power alone does not establish it.

> "The device, when it is an infrared therapeutic heating lamp, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9."
>
> 21 CFR 890.5500, as in force on July 22, 2025. Last amended 84 FR 71818, Dec. 30, 2019

Product codes

CODE	WHY IT FITS	CLASS	FDA'S RULE	510(K)S	LAST 5 YRS	DE NOVO, PMA
NHN Best fit	**Powered Light Based Laser Non-Thermal Instrument With Non-Heating Effect For Adjunctive Use In Pain Therapy** Best fit for your laser-based adjunctive pain claim if treatment-plane dosimetry and thermal testing confirm a non-heating effect.	II	510(k)	51	8	0
ILY Alternate	**Lamp, Infrared, Therapeutic Heating** Fits therapeutic heating, which your design has not established; its exemption would require a separate assessment against the final design and exemption limits.	II	510(k) exempt	228	6	0
GEX Alternate	**Powered Laser Surgical Instrument** Its tissue-cutting, destruction, removal or coagulation scope does not match your stated pain-relief claim.	II	510(k)	2,795	304	0

FDA files near-identical devices under different codes, so we searched all three for predicates. Your code is decided by FDA, and a predicate can sit in a neighbouring code. Companies sometimes file 510(k)s in exempt codes, so a code's 510(k)s do not show a 510(k) is required.

Codes we ruled out

IOB	**Lamp, Infrared, Non Heating.** Its non-heating infrared description is less specific than NHN, and FDA's reviewed examples do not establish a close pain-therapy match.
NZY	**Light, Lymphedema Reduction, Low Energy.** Addresses low-energy laser treatment of post-mastectomy lymphedema, not your musculoskeletal neck and shoulder pain claim.
ONE	**Powered Light Based Non-Laser Surgical Instrument.** Covers non-laser light-based instruments, whereas your device uses laser diodes.

3 Ranked candidate predicates

A predicate needs the same intended use, and technology that raises no new questions. We read 83 matches in full, and these ten came closest.

1,297	109	83	10
cleared devices found in 15 years of records	scored strong on name and indications	of those with an FDA summary, read in full	ranked here for you

Our provisional predicate is K241057, shaded below. K241057 is your provisional predicate because it combines handheld red/infrared lasers with the neck/shoulder pain indication; its power, delivery and dosing differences need support.

	NUMBER	DEVICE	FIT /5	DOCUMENTED	CITED BY	GENS	RECALLS
1	K241057	**Enhanced Handheld Pain Relief Laser Instrument** Wuhan Guangdun Technology Co.,Ltd.., 2025 · NHN	4.0	7/11	0	5	0
2	K212595	**Erchonia FX-405** Erchonia Corporation, 2021 · NHN · predicate of K231409	3.5	8/11	1	3	0
3	K211186	**Erchonia XLR8** Erchonia Corporation, 2021 · NHN · predicate of K231409	3.5	8/11	1	1	0
4	K231409	**Erchonia FX-405** Erchonia Corporation, 2023 · NHN	3.5	7/11	0	4	0
5	K221987	**Erchonia GVL** Erchonia Corporation, 2022 · NHN	3.5	7/11	0	2	0
6	K190572	**Erchonia FX-635** Erchonia Corporation, 2019 · NHN · predicate of K212595	3.5	7/11	1	2	0
7	K191257	**Erchonia EVRL** Erchonia Corporation, 2019 · NHN · predicate of K221987	3.0	7/11	1	1	0
8	K180585	**Collagentex Rx-6** Tanses Technologies, Inc., 2018 · NHN	3.0	7/11	0	2	0
9	K162022	**Collagentex Rx-1** Tanses Technologies, Inc., 2016 · NHN · predicate of K180585	3.0	7/11	1	1	0
10	K142256	**Applied BioPhotonics Phototherapy System** Applied Biophotonics, Ltd., 2015 · ILY	2.5	7/11	0	11	0

Also read: devices the leaders claim as their predicates

	NUMBER	DEVICE	FIT /5	DOCUMENTED	CITED BY	GENS	RECALLS
12	K050668	**GRT Lite** Grt Solutions, Inc., 2006 · NHN · predicate of K241057	2.5	6/11	2	4	0
79	K030226	**Thor Ddii 830CL3 Laser System** Thor Intl., 2003 · NHN · predicate of K241057	2.0	5/11	4	2	0

Ranked on fit to your device, judged from reading each summary: 5 is the same intended use and the same kind of technology. Ties go to the summary that documents more of the 11 attributes compared in section 4, then to the newer device. Citations, generations and recalls are context, not points: a device many cite, or none has recalled, is not for that a closer match. The recommendation weighs the side-by-side differences. Counts are as of July 22, 2025.

Close matches with no FDA summary

FDA holds only a short statement for these, so their technology could not be compared. Their indications, dates, recalls and listed models are in FDA's records, and the company can share the rest.

NUMBER	DEVICE	WHY IT IS HERE	RECALLS
K130996	**Erchonia Emerge** Erchonia Medical, Inc., 2013 · NHN Listed in FDA's device identifier database as 1 model (1 non-sterile), such as VLS: veterinary - handheld low level laser - 2 diodes 640nm 10mw -....	Predicate of K241057, K211186	0
K152196	**Erchonia EVRL** Erchonia Corporation, 2016 · NHN	Predicate of K221987	0
K012580	**Erchonia PL2000** Tuco Innovations, Inc., 2002 · NHN	Predicate of K241057, K221987	0
K041139	**Erchonia Eml Laser** Erchonia Medical, Inc., 2004 · NHN	Predicate of K211186	0
K072206	**Erchonia Eml Laser** Erchonia Medical, Inc., 2008 · NHN	Predicate of K211186	0
K250195	**MateLaser Medical Laser Therapy Systems (ML-HIL-30** Matelaser, Inc., 2025 · GEX	Strong match on name and indications	0

4 Side-by-side comparison

Attribute	Your device	K241057 **Enhanced Handheld Pain** Wuhan Guangdun Technology Co.,Ltd.., 2025	K212595 **Erchonia FX-405** Erchonia Corporation, 2021	K050668 **GRT Lite** Grt Solutions, Inc., 2006
Intended use	Adjunctive temporary relief of minor chronic musculoskeletal neck and shoulder pain.	Adjunctive temporary relief of minor chronic musculoskeletal neck/shoulder pain and carpal tunnel syndrome pain. Similar p.4	Adjunctive temporary relief of nociceptive musculoskeletal pain. Similar p.5	Adjunctive temporary relief of chronic musculoskeletal neck/shoulder pain and carpal tunnel syndrome pain. Similar p.2
Indications and patient population	Patients with minor chronic musculoskeletal neck and shoulder pain; age range not stated.	Patients with chronic musculoskeletal neck/shoulder pain or carpal tunnel syndrome pain; ages unspecified. Similar p.4	Nociceptive musculoskeletal pain; age range not stated. Similar p.3	Patients with musculoskeletal neck/shoulder pain or carpal tunnel syndrome pain; ages not stated. Similar p.2
Intended users and prescription status	Prescription device for doctors, nurses, and physical therapists.	Prescription use only; specific professional users not stated. Similar p.7	Prescription use; specific professional users not stated. Similar p.3	Prescription use; specific professional users not stated. Similar p.6
Intended use setting	Not stated	Not stated	Not stated	Not stated
Device configuration	Handheld therapeutic laser with holder, charging cable, spacers, eye protection, and carrying case.	Handheld instrument with LCD, button, battery, charger jack, power cords, and power adapter. Similar p.6	Wall-powered mobile base with adjustable arm, four laser heads, touchscreen, and protective eyewear. Differs p.5	Handheld, battery-operated control unit with four LEDs and a red acrylic lens. Similar p.2
Laser sources and wavelengths	660 nm red laser diode and 808 nm infrared laser diode.	650 nm and 808 nm laser wavelengths. Differs p.6	Three red diodes, nominally 635 nm; one violet diode, nominally 405 nm. Differs p.4	Two visible LEDs at 628nm (±5%); two infrared LEDs at 850nm (±5%). Differs p.2
Optical output, delivery, and control	Each diode delivers 100 mW through optical fibers; output controlled by electrical current.	650 nm: 5 mW; 808 nm: 3 mW; handheld probe; fiber/current control unspecified. Differs p.7	Red: 17.25 mW/diode; violet: 23 mW; lens delivery; output not user-adjustable. Differs p.5	Light delivered through red acrylic lens; numerical output and current control not stated. Differs p.2
Continuous or pulsed emission and diode sequencing	Not stated	Pulsed and continuous modulation; diode sequencing not stated. p.7	Variable-hertz pulsed wave with preprogrammed breaks. p.5	Six pulsed/continuous modes with visible/infrared combinations; one visible LED always on. p.3

Attribute	Your device	K241057 **Enhanced Handheld Pain** Wuhan Guangdun Technology Co.,Ltd.., 2025	K212595 **Erchonia FX-405** Erchonia Corporation, 2021	K050668 **GRT Lite** Grt Solutions, Inc., 2006
Treatment session duration	Sessions last 1–8 minutes; three consecutive 8-minute sessions permitted, totaling 24 minutes.	5 or 8 minutes; consecutive-session allowance not stated. **Differs** p.7	Neck/shoulder protocol: single treatment totaling 13 minutes; other condition-specific protocols also described. **Differs** p.8	Not stated
Treatment separation and patient-contact material	Polycarbonate spacer maintains tip-to-skin separation and is the only patient-contacting component.	Not stated	No contact with patient skin or other bodily tissue. **Differs** p.7	Not stated
Beam geometry, spot size, irradiance, and fluence at skin	Not stated	Spot 1.16 mm^2 average; irradiance 3.43–4.95 mW/mm^2; fluence 1773.15 mJ/mm^2; skin location unspecified. p.7	Line-refracted light forms random spiraling circles; numerical spot size not stated. p.5	Not stated

Each cell compares the cleared device with yours. Differences are shaded. Page numbers link to FDA's summary.

> K241057 uses thirteen 650 nm and four 808 nm diodes with listed powers of 5 mW and 3 mW, versus your 660/808 nm diodes at 100 mW each through fibers. Its 5-or 8-minute treatments do not establish support for your permitted 24-minute consecutive exposure, and its summary leaves spacer contact and fiber delivery unstated.

Differences a reviewer would raise

K241057

- The cleared device additionally claims temporary relief of minor chronic pain associated with carpal tunnel syndrome.
- The cleared device uses thirteen 650 nm and four 808 nm diodes, with listed powers of 5 mW and 3 mW, versus two proposed 660/808 nm diodes delivering 100 mW each through fibers.
- The cleared device lists 5-or 8-minute treatments; the proposal permits 1–8 minutes and three consecutive 8-minute sessions.

K212595

- Broader nociceptive musculoskeletal pain indication and additional low-back and plantar-fasciitis treatment protocols versus neck/shoulder-only claims.
- Three 635 nm red diodes and one 405 nm violet diode at lower powers versus 660/808 nm diodes delivering 100 mW each.
- Noncontact floor-standing scanning optics and a 13-minute neck/shoulder protocol versus handheld fiber delivery, skin-contact spacer, and 1–8-minute sessions.

K050668

- Four 628nm/850nm LEDs versus two 660nm/808nm laser diodes; pulsed and continuous operating modes are described.
- Red acrylic lens delivery versus optical fibers and a polycarbonate spacer; equivalent output and skin dose are not established.
- The cleared device additionally claims carpal tunnel syndrome pain relief, which the proposal does not claim.

5 What FDA saw from these devices

Each summary lists the testing behind its clearance. This is the closest public record of what your file will need.

TESTING REPORTED	K241057	K212595	K211186	K231409	K221987	K190572	OF 10	STANDARDS NAMED
Electrical safety	●	●	●	●	●	●	10	IEC 60601-1, IEC 60601-1-11
EMC	●	●	●	●	●	·	8	IEC 60601-1-2
Software	●	●	·	●	·	●	6	IEC 62304
Bench performance	●	·	·	·	·	·	3	—
Shelf life, packaging	·	·	·	·	·	●	2	IEC 60601-1
Human clinical data	·	●	·	·	●	●	4	—

Columns show the top six candidates. “Of 10” counts every ranked device. A dot means the summary reports that testing, confirmed by a quote on the cited page.

> K241057 reports electrical safety, electromagnetic compatibility, software and bench testing without a human clinical study, while K221987 submitted human clinical data and K212595 relied on previously reviewed clinical data. Plan electrical and electromagnetic compatibility testing, applicable software verification, optical dosimetry, thermal testing, eye-protection verification and spacer-contact evaluation, then resolve whether your delivery and dose differences require clinical support rather than assuming K241057's testing approach is sufficient.

6 Family-tree risk

A reviewer can trace a predicate back through the devices it was compared with. Their recalls are part of the record your device will join, though they do not decide equivalence.

K241057 Enhanced Handheld Pain Relief Laser

Its longest line of descent runs back 5 generations to K001179 (2000). 11 ancestors in all. No later device cites it as a predicate yet.

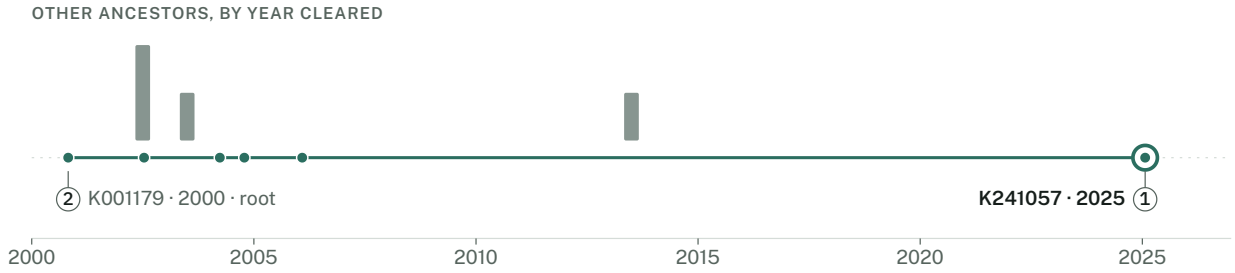


FIG. 1 — Lineage of K241057 to 2025. Source: FDA 510(k) summaries.

K050668 GRT Lite

Its longest line of descent runs back 4 generations to K001179 (2000). 7 ancestors in all. 8 later devices descend from it, 2 citing it directly.

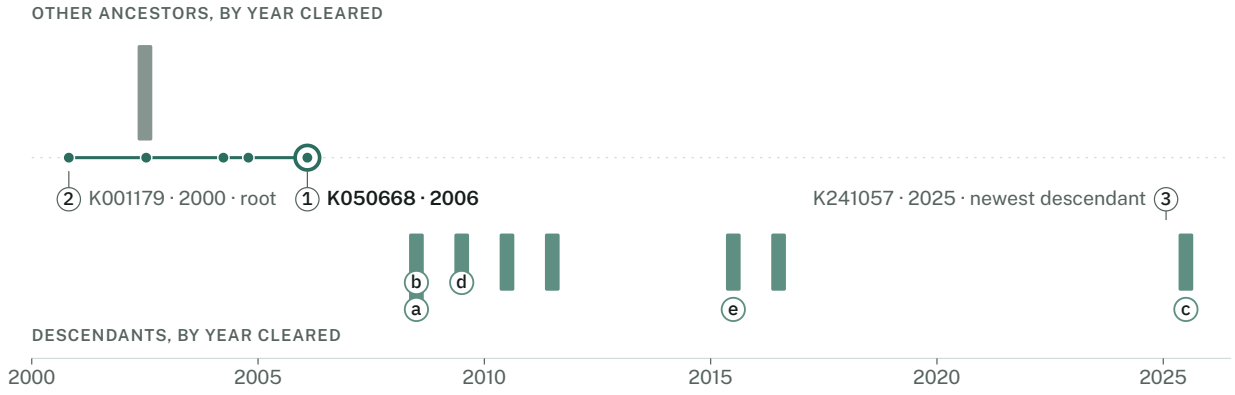


FIG. 2 — Lineage of K050668 to 2025. Source: FDA 510(k) summaries.

FIG. 1 and 2 draw the families of K241057 and K050668. The recall record below covers all 3 compared devices, including K212595.

Line of descent: each device cites the next Other ancestors, by year Class I recall

> K241057 cites K050668, K030226, K130996 and K012580; among the read predicates, K050668 uses LEDs and K030226 addresses carpal tunnel hand/wrist pain, making K241057 the better device for you to claim. Its 12-device, five-generation family has no recorded recalls, but that history does not resolve your output, delivery or exposure differences.

No device in the families of K241057, K212595 and K050668 had a recall by July 22, 2025.

7 Review-time outlook

How long Traditional 510(k)s in these codes took from receipt to decision. Plan around the spread as well as the median.

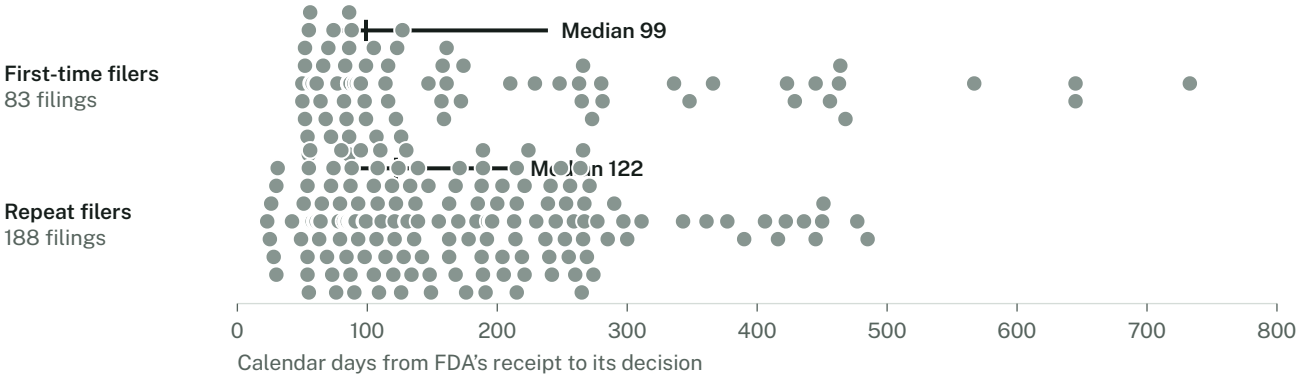


FIG. 3 — Every Traditional 510(k) decided in these codes in the five years to July 22, 2025. Bar: the middle half. Tick: the median.

GROUP	FILINGS	MEDIAN	MIDDLE HALF	9 IN 10 WITHIN	OVER 300	LONGEST
All three codes	271	114	85–217	311	28	733
NHN only	8	233	—	—	—	463
First-time filers	83	99	80–239	442	14	733
Repeat filers	188	122	87–215	275	14	485
Whole physical medicine panel, 5 years	379	162	90–261	424	68	1278

For your 510(k), plan around 114 calendar days from FDA receipt to decision, with the middle half at 85–217 days and a 90th percentile of 311 days, based on 271 Traditional 510(k)s across NHN, ILY and GEX combined (only 8 were in NHN) during the five years before July 22, 2025. These figures include applicant response time but exclude submission preparation; your filing experience and target filing date are unstated, so we cannot assess schedule fit.

By year of decision

YEAR	FILINGS	MEDIAN	MIDDLE HALF
2020	13	107	79–147
2021	46	143	88–262
2022	59	157	89–283
2023	45	90	84–191
2024	71	99	81–173
2025	37	116	88–215

These are calendar days from receipt to decision, including any time the applicant spent answering FDA's questions. FDA's own goal is a decision on 95% of 510(k)s within 90 FDA days, a clock that stops while FDA waits for those answers, so its figures run shorter than these. First-time filers are companies with no earlier 510(k).

8 Post-market record

What has gone wrong with devices in NHN, and what to design against from day one.

Adverse event reports per year, NHN

4 reports, 3 since 2014



Recalls, NHN

2 in all, latest 2019

Class III	2

No Class I recall on file. FDA's data gives no class for most recalls before 2012.

> The two Class III recalls under NHN on September 26, 2019 concern Theralase's K151816 system and its power pack, not the K241057, K212595 or K050668 families, which have no recorded recalls; missing UDI labels and an additional power-pack CE-marking issue call for identification and labeling checks at release. NHN's four adverse event reports concern different products and do not establish causation for your device, but they support checking exposure limits, skin-reaction precautions and stop-treatment instructions.

What adverse event reports describe

REPORT	BRAND	TYPE	WHAT THE REPORT DESCRIBES
Mar 26, 2025 MW5168282	Laser Device	Injury	Fingers developed pale scars after 20 minutes of laser exposure.
Apr 13, 2021 MW5100775	Red Light Laser Treatment	Injury	Adverse reaction reported after red-light laser treatment; specific symptoms not stated.
Jul 31, 2019 MW5088700	Tristar One-Photons System	Injury	Severe rash and asthma flare after LED therapy required cortisone and steroid treatment.
Jun 23, 2010 MW5016476	Not named	Injury	Facial light therapy caused nausea, sweating, shaking, near-fainting, and inability to drive.

Of 4 adverse event reports in NHN, 4 from every year on file carry a narrative, and we read all 4. Too few to group into themes, so each is listed as one report's account, not a pattern. Each report number opens FDA's MAUDE record of it.

Recalls in NHN

DATE	CLASS	COMPANY AND REASON	RECALLS
Sep 26, 2019	III	**Theralase Inc.** Device was shipped without a Unique Device Identification (UDI) label. Root cause: Process control.	2

The alternate codes, counted apart

These codes hold other kinds of devices too, so their records are not in the figures above.

CODE	DEVICE TYPE	ADVERSE EVENT REPORTS	LAST 3 YEARS	RECALLS	CLASS I
ILY	Lamp, Infrared, Therapeutic Heating	267	45	12	0
GEX	Powered Laser Surgical Instrument	40,895	7,012	83	1

Counts are reports filed, not rates. FDA publishes no denominator of devices in use.

9 Assessment and next steps

Our reading of what the records mean for your device. Tags show where a statement rests:

IN FDA'S RECORDS
A record states it.

OUR JUDGMENT
We drew it from the records.

NEEDS YOUR INPUT
It turns on something you have not told us yet.

We recommend NHN for your adjunctive pain claim, subject to confirming a non-heating effect. Section 890.5500 limits its exemption to infrared therapeutic heating lamps; it does not exempt NHN's non-heating type. If topical heating instead explains your therapeutic effect, reassess ILY and its exemption limits. ILY is not an inferior classification because it is exempt, but its heating mechanism is not established for your design.

Claim K241057 provisionally because it best combines your pain indication, handheld configuration and red/infrared laser technology. K212595 and K211186 document more comparison details, but their wavelengths and delivery differ more from yours. Keep your claim limited to neck and shoulder pain rather than adding K241057's carpal tunnel indication. Final treatment-plane output, emission mode, diode sequencing, beam geometry, spacer distance and treatment course will confirm or change this choice.

K250195, K231997 and K190034 are also likely predicates based on their close name and indication matches, but their stated topical-heating uses make them less aligned with the proposed NHN classification. FDA holds only short statements for them, so a 510(k) relying on one would need a technical comparison from the company's own records or FDA's file. Resolve their heating mechanism and delivery specifications before replacing K241057.

Risks

The therapeutic mechanism could change classification

Your 100 mW per diode specification does not establish a non-heating effect because treatment-plane irradiance, fluence and thermal performance are unknown. NHN describes non-heating pain therapy, while ILY describes therapeutic heating.

NEEDS YOUR INPUT

Measure output and temperature at the skin under the final treatment protocol, including the permitted consecutive sessions, and document why the measured effect supports NHN.

Output and exposure differences may prevent equivalence

K241057 lists substantially lower per-diode powers and 5- or 8-minute treatments, while you propose 100 mW per diode and consecutive sessions totaling 24 minutes. Neither comparable skin dose nor equivalent delivery has been established. OUR JUDGMENT

Compare treatment-plane irradiance, fluence, beam geometry, output tolerances and cumulative exposure, then ask FDA whether bench support is sufficient or clinical data are needed.

Patient-contact and protective controls remain undefined

Only your polycarbonate spacer contacts skin, but its dimensions, reuse status and cleaning or disposal instructions are unstated. Laser safety classification, wavelength-specific eye protection and power/charging configuration also remain open. NEEDS YOUR INPUT

Define these features before testing; evaluate spacer contact safety, applicable cleaning or disposal instructions, optical protection, electrical safety and the final charging configuration.

Ancestor records do not establish reviewed technology

FDA holds only short statements for K130996 and K012580. Under K130996, the company's GUDID listing describes a veterinary handheld model with two 640 nm, 10 mW diodes; that listing does not establish the human-use configuration FDA reviewed. OUR JUDGMENT

Keep K241057 as the provisional lead and obtain the relevant technical files before relying on either ancestor to support your technology comparison.

Reported injuries warrant exposure and reaction controls

Individual reports describe pale finger scars after 20 minutes of laser exposure; an unspecified adverse reaction after red-light treatment; severe rash and an asthma flare after LED therapy; and nausea, sweating, shaking, near-fainting and inability to drive after facial light therapy. No brand dominates these four reports. IN FDA'S RECORDS

Challenge the maximum permitted exposure and define skin-reaction warnings and stopping criteria, while recognizing that these reports do not establish the cause or frequency of injury for your design.

Questions for a Pre-Submission

1. Once treatment-plane dosimetry and thermal results are available, does FDA agree that the final device fits NHN's non-heating pain-therapy type rather than ILY's therapeutic-heating type?
2. Does FDA agree that K241057 can support substantial equivalence despite our 660/808 nm, 100 mW-per-diode fiber delivery, skin-contact spacer and permitted 24-minute consecutive exposure?
3. What optical-output, thermal and eye-protection testing would FDA expect for the final continuous or pulsed emission mode and simultaneous or sequential diode operation?
4. Would comparative bench testing support the neck/shoulder pain claim, or do the final dose, delivery and treatment-course differences require a clinical study?
5. Does FDA agree with the proposed spacer-contact evaluation and, once reuse status is fixed, the cleaning, disinfection or disposal validation plan?

Next steps

1. **Finalize intended use and treatment design.** Set patient ages and exclusions, professional use setting, treatment placement, frequency, course, emission mode, diode sequencing and reuse status.
2. **Confirm non-heating performance and NHN classification.** Define treatment-plane output, tolerances, beam geometry and spacer distance; measure dose and temperature under the maximum permitted exposure.
3. **Build the K241057 comparison and testing plan.** Explain each output, delivery, contact and dosing difference, and obtain additional technical records where the summaries leave material gaps.
4. **Resolve key questions through a Pre-Submission.** Seek FDA feedback on classification, the proposed predicate, comparative testing and the need for clinical support.
5. **Complete testing and clinical justification.** Finish applicable electrical, electromagnetic compatibility, software, optical, thermal, patient-contact and reuse evaluations, with clinical support if needed.
6. **Submit your Traditional 510(k).** Use the final design, supported treatment protocol, justified predicate comparison and completed testing.

10 What applies either way

Whether or not your device needs a 510(k), these FDA requirements apply once you sell it in the US.

Before you sell

REQUIREMENT	WHAT TO DO	RULE
Register and list	If you make the device in the US, register your establishment and list the device within 30 days of starting production. If you make it abroad, register and list before it is first offered for import, and name a US agent. Renew each year between October 1 and December 31. Registration carries an annual user fee.	21 CFR 807.22, 807.40
Quality management system	Document a quality system under FDA's Quality System Regulation. From February 2, 2026 the rule incorporates ISO 13485 instead. As a Class II device, it also needs design and development controls (ISO 13485 clause 7.3).	21 CFR 820.10
Labeling	Label the device under FDA's labeling rule, with the prescription statement for a device sold only on a practitioner's order.	21 CFR part 801, 801.109
Unique device identifier	Put a UDI on the label and on every device package, and send the device's record to FDA's GUDID database.	21 CFR 801.20, 801.30, part 830

Once you sell

REQUIREMENT	WHAT TO DO	RULE
Adverse event reports	Report to FDA within 30 calendar days of learning that the device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would be likely to if it happened again. Report within 5 work days when an event needs action to prevent unreasonable risk of substantial harm. This code is eligible for FDA's voluntary program for reporting malfunctions in quarterly summaries.	21 CFR 803.50, 803.53
Corrections and removals	Report to FDA within 10 working days of starting a correction or removal made to reduce a risk to health.	21 CFR 806.10

When you file

REQUIREMENT	WHAT TO DO	RULE
Submission format	Send the 510(k) through FDA's eSTAR template and pay the 510(k) user fee. A company FDA qualifies as a small business pays less.	FD&C Act 745A(b), 738

From FDA's rules as of July 22, 2025, for this code and class. They are not every rule that can apply; the rule cited is the place to start.

11 Sources and method

We picked the product codes your request fits and read the regulation behind them as it stood on July 22, 2025. We screened every clearance in those codes, and every one whose name or indications matched, back 15 years. We read the FDA summary of every strong match, and of the devices the leaders claim as predicates, however old, then ranked them on fit as section 3 explains. Products you named we traced by maker, by recalls that list their clearance, and in FDA's device identifier database.

AI models did the reading, and every value came back with a quote and a page. A script found all 994 quotes in FDA's text; a quote shows the words are there, not that we read them rightly, so each cell in section 4 links to its page. Scripts checked that the pathway follows FDA's rule for your code, that every product you named is accounted for, that the predicate was compared with the device it claims and that every total adds up; a second model read the writing against the tables for contradictions. Predicate links come from our reading of more than 92,000 FDA documents (510kreport.com/methodology).

Records used, all cut at July 22, 2025: FDA's classification database, the eCFR, FDA's 510(k), De Novo and PMA databases and summaries, recall records, MAUDE adverse event reports, and FDA's device identifier database (GUDID, via openFDA; listings as kept today, first published before that date). Device and report numbers link to FDA's records, and rules to the eCFR as it read then.

DEMONSTRATION CHECK

How this report held up

We wrote the request from the public record of Therapy US from Dmc Importação E Exportação DE Equipamentos Ltda, K252273, and hid that device and everything after July 22, 2025. FDA cleared it on December 12, 2025. The company did not commission or review this report.

	THIS REPORT SAID	WHAT HAPPENED
Product code	NHN, with ILY and GEX as alternates	FDA classified it under NHN
Predicate	Claim K241057. Top three by rank: K241057, K212595, K211186	Cited K241057, Enhanced Handheld Pain Relief Laser. This report ranked it **#1 of 83** read, fit 4.0 against 4.0 for the first. That device's own predicate, K050668, is #12 here, and section 9 names it as a comparator.
Testing	Plan for 4 test areas reported by at least five of the top ten	Reported 6 test areas, 3 of them on the plan: Electrical safety, EMC, Bench performance, Software, Cybersecurity, Biocompatibility
Clinical data	4 of the top ten submitted human clinical data	No clinical testing submitted
Review time	Median 114 days. 28 of 271 ran past 300	**143 days**, beyond 160 of the 271 comparable reviews

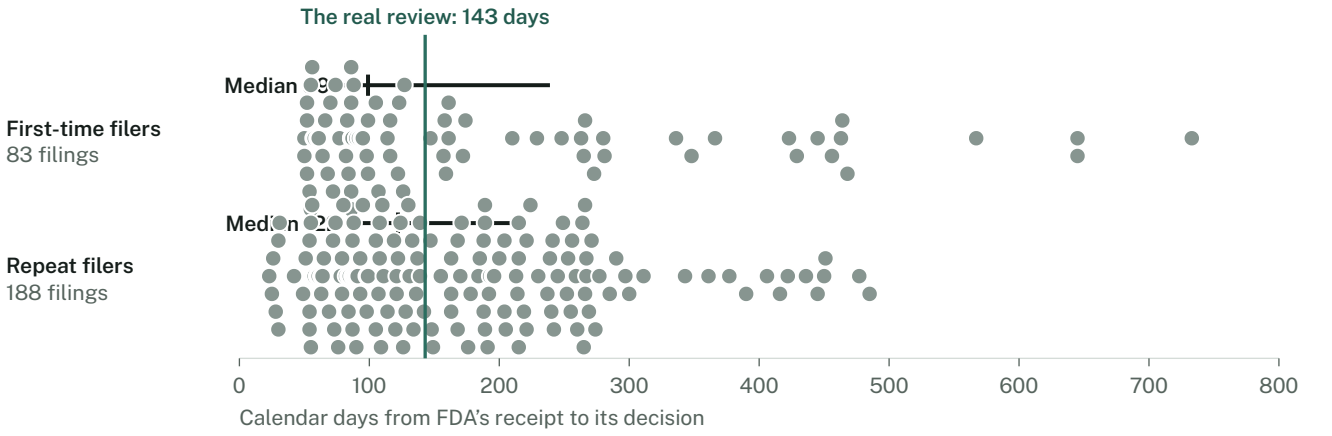


FIG. 4 — FIG. 3 again, with the real review marked.

How to read this. Blind test. We wrote this request from the public summary of a real device, with every name and number left out, froze FDA's records on the day FDA received its 510(k), and compared the report with FDA's decision only after it was built. One device is one result, not a hit rate.