

PATHWAY REPORT

Over-the-Counter Fingertip Pulse Oximeter

Pathway

A fingertip pulse oximeter sold over the counter at pharmacies and online. Adults with COPD use it at home to spot-check their blood oxygen level and pulse rate, and call their doctor if the reading drops. Two AAA batteries, reusable, no alarms, no app.

DRAFT Prepared by software from FDA records on 2026-09-24 and read by a second model. It proposes; a regulatory professional decides. Not regulatory or legal advice.

PROPOSED PRODUCT CODE OLK Pulse Oximeter For Over-The-Counter Use HIGH	REGULATION 21 CFR 870.2700 · Class 2	PROPOSED PATHWAY 510(k) HIGH The route FDA has on record for OLK
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HIGH the FDA record says it outright · **MEDIUM** the record plus one inference · **LOW** a reading of the description; check it

What a 510(k) means

You show FDA the device is substantially equivalent to one already on the market: the same intended use, and technology that raises no new questions of safety and effectiveness.

FDA's review goal	A decision within 90 FDA days; days waiting on you do not count
FDA fee from Oct 1, 2026	\$28,653, or \$7,163 as a small business
Small business saving	\$21,490, with gross receipts of \$100 million or less
Every year after launch	Establishment registration, \$13,785 (no small-business rate)

Small business rate. Qualify first, then pay: send FDA Form 3602N with your latest tax return (and any affiliates') through the CDRH Portal. FDA aims to decide within 60 days, and the status lasts one fiscal year, to September 30, so apply in the year you submit.
[How to apply](#)

Sources: FDA user fees for FY2027 (Federal Register, July 30, 2026), MDUFA V performance goals, FDA small business program.

What to confirm next

The 13 checks a regulatory consultant would make, in the order of the report.

1 · CLASSIFICATION

- Confirm the final labeling preserves OTC spot-check use and does not add diagnosis, screening, treatment-decision or continuous-monitoring claims.
- Confirm the precise intended population, measurement performance and use conditions against the OLK clearances and relevant 510(k) summaries.
- Confirm whether the final product design includes any alarms, wireless functions or other features not stated in the description.

2 · PREDICATES

- Review the complete summaries and indications for use for the four kept predicates before fixing the comparison or final claim language.
- Assess whether the MAUDE and recall hazards are relevant to the final design, labeling and home-use risk controls.

3 · EQUIVALENCE TABLE

- Obtain full predicate comparison tables and reports before relying on numerical performance or testing details omitted from the excerpts.
- Determine which predicate testing is applicable to the final device's two-battery design, materials, software and intended home-use conditions.

4 · STANDARDS

- Confirm the current recognition status, scope and applicable edition for each selected standard before planning testing.
- Confirm battery chemistry and the final patient-contact materials to resolve conditional standards.

5 · OBLIGATIONS

- Confirm applicability of registration, listing, UDI, quality-system and postmarket requirements to the manufacturer's role and final distribution arrangement.
- Confirm the proposed label and directions are consistent with OTC spot-check use and the final claims.

6 · PLAN AND BUDGET

- Confirm with a test lab that the clinical accuracy study can be run to the current FDA recommendations on skin pigmentation before fixing the budget.
- Confirm the Basic software documentation level against FDA's software guidance once the risk analysis exists.

We assumed: The stated spot-check use is intermittent rather than continuous monitoring. The device measures oxygen saturation optically through a fingertip, as is inherent in the described pulse oximeter type.

Questions that would sharpen this report

- MEDIUM: What oxygen-saturation accuracy will you claim, and over what range?
- MEDIUM: What ages will the label say it is for?
- MEDIUM: Will the label claim anything beyond spot checks and calling a doctor?
- LOW: What does the screen show besides the two numbers?

Answer any of them on the report's web page and we will email you an updated report. HIGH could change the product code or the pathway; MEDIUM could change the devices to compare with, the standards or the tests; LOW fills in a detail.

1. Classification and pathway

OLK (pulse oximeter for over-the-counter use) specifically covers a non-wearable fingertip pulse oximeter used OTC for non-continuous monitoring, matching the stated device and use. HIGH

CODE	DEVICE NAME	REGULATION · PREMARKET	FITS?	WHAT DISTINGUISHES IT	CONF.
QWE	Hyperoxia Monitoring Device Adjunct To Pulse Oximetry	870.2720 · 510(k)	no	QWE (hyperoxia monitoring device adjunct to pulse oximetry) monitors elevated hemoglobin oxygen saturation as an adjunct, while this device spot-checks oxygen saturation and pulse rate.	HIGH
QYU	Infant Pulse Rate And Oxygen Saturation Monitor For Over-The-Counter Use	870.2705 · 510(k)	no	QYU (infant pulse rate and oxygen saturation monitor for OTC use) is intended for infants, while the stated users are adults with COPD.	HIGH
OLK	Pulse Oximeter For Over-The-Counter Use	870.2700 · 510(k)	yes	The proposed code, for the reason above.	HIGH
MUD	Oximeter, Tissue Saturation	870.2700 · 510(k)	no	MUD (oximeter, tissue saturation) is exemplified by devices measuring regional tissue saturation, while this device is described as measuring blood oxygen saturation at a fingertip.	HIGH

QVT	Monitor For Opioid Induced Impairment Of Oxygenation	868.2250 · 510(k)	no	QVT (monitor for opioid induced impairment of oxygenation) detects desaturations resulting from opioid overdose, a purpose not stated for this COPD spot-check device.	HIGH
OUW	Infant Positioner, Rx, Use In Highly Monitored Setting	880.5680 · 510(k)	no	OUW (infant positioner, Rx, use in highly monitored setting) is an infant positioning device rather than an oximeter.	HIGH
MMA	Oximeter, Fetal Pulse	· PMA	no	MMA (oximeter, fetal pulse) concerns fetal oxygen saturation monitoring, while the stated users are adults.	HIGH
NMD	Oximeter, Tissue Saturation, Reprocessed	870.2700 · 510(k)	no	NMD (oximeter, tissue saturation, reprocessed) is for reprocessed devices, and this product is described as a reusable device rather than a reprocessed device.	HIGH
PGJ	Oximeter, Wellness	870.2700 · Enforcement discretion	no	PGJ (oximeter, wellness) is for wellness use, while this device is intended for adults with COPD to monitor blood oxygen and contact their doctor when a reading drops.	HIGH
DQA	Oximeter	870.2700 · 510(k)	maybe	DQA (oximeter) is a broader oximeter code that covers related pulse oximeters, but OLK is preferred because its definition specifically matches OTC fingertip, non-continuous use.	HIGH
QEM	Cerebral Oximeter	870.2700 · 510(k)	no	QEM (cerebral oximeter) measures cerebral tissue saturation, not fingertip blood oxygen saturation.	HIGH
KLK	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia	868.2500 · 510(k) exempt	no	KLK (monitor, oxygen, cutaneous, for infant not under gas anesthesia) uses a heated skin sensor to monitor cutaneous oxygen tension, not fingertip pulse oximetry.	HIGH
CCE	Analyzer, Gas, Oxygen, Partial Pressure, Blood-Phase, Indwelling	868.1200 · 510(k)	no	CCE (indwelling blood oxygen partial pressure analyzer) measures in-vivo blood oxygen partial pressure with a catheter-tip transducer, not fingertip oxygen saturation.	HIGH
NLF	Oximeter, Reprocessed	870.2700 · 510(k)	no	NLF (oximeter, reprocessed) is for reprocessed oximeters, whereas the description does not identify this product as reprocessed.	HIGH
DQE	Catheter, Oximeter, Fiber-Optic	870.1230 · 510(k)	no	DQE (fiberoptic oximeter catheter) estimates blood oxygen saturation using a catheter, unlike this external fingertip device.	HIGH
OCH	Oximeter, Infrared, Sporting, Aviation	870.2700 · Enforcement discretion	no	OCH (oximeter, infrared, sporting, aviation) is solely for sporting and aviation activities, while this product is intended for home medical monitoring by adults with COPD.	HIGH

Pathway

Proposed: 510(k). OLK is Class II and not 510(k) exempt, and its definition expressly covers OTC fingertip pulse oximetry for non-continuous monitoring; the described medical use falls within that intended-use category. **HIGH**

- **Why not De Novo:** De Novo is not proposed because OLK covers this OTC, fingertip, non-continuous monitoring use.
- **Why not PMA:** PMA is not proposed because the best-fitting candidate OLK is Class II, not Class III.

What would change the answer

IF	THEN	CONF.
The labeled use were limited to wellness without a medical purpose.	Reassess whether the product is a medical device and whether PGJ (oximeter, wellness) is the relevant reference.	MEDIUM
The device were intended for continuous monitoring or for a different patient population or clinical purpose.	Reassess whether OLK still covers the intended use and whether another product code is more appropriate.	MEDIUM

3 checks for this section are under What to confirm next, at the start of this report.

2. Predicates, ranked with reasons

Ranked by closeness of intended use, then technology and recency; kept predicates have summaries in the FDA records. K211498 and K214115 are OLK OTC fingertip spot-check predicates, while the DQA examples provide related technical and safety comparisons. The summaries for K211498, K214115, K252805 and K252448 are available; no higher-ranked candidate lacks a summary.

Kept

K NUMBER	DEVICE (APPLICANT)	DECISION	WHY KEPT	CONF.
K211498	Nonin OTC Pulse Oximeter Model 3250 (Nonin Medical, Inc.)	2024-11-13 · Cleared	Nonin Model 3250 OTC Pulse Oximeter (K211498) is an OTC fingertip pulse oximeter for adult spot-checking of SpO2 and pulse rate and is the closest match to the described intended use.	HIGH
K214115	MightySat -OTC (Masimo Corporation)	2024-01-31 · Cleared	MightySat-OTC (K214115) is a fingertip device for OTC spot-checking of SpO2 and pulse rate in adults, with no-motion use specified.	HIGH
K252805	YUWELL® Finger Pulse Oximeter (YX105, YX106, YX110, YX310) (Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.)	2026-02-17 · Cleared	YUWELL® Finger Pulse Oximeter (K252805) is a reusable fingertip spot-check device for home and professional settings, though its stated population includes adults and children and its description does not establish the same OTC indication.	HIGH
K252448	AViTA Pulse Oximeter (SP61) (Avita Corporation)	2026-02-27 · Cleared	AViTA Pulse Oximeter (K252448) is a spot-check device for SpO2 and pulse rate in home and professional settings, but its summary states prescription use and a broader age group.	HIGH

15 devices considered and set aside

510(K)	DEVICE	WHY DISCARDED
K234021	Masimo Stork	Masimo Stork (K234021) is a wearable infant and neonatal monitor for spot-checking and continuous monitoring, not an adult fingertip spot-check device.
K243324, K254129, K214072	Masimo O3 Regional Oximeter and 2 more	The listed MUD examples concern regional or tissue oxygenation, not fingertip measurement of arterial hemoglobin oxygen saturation.
K201976, K211561	SnapshotNIR and 1 more	These MUD examples concern tissue oximetry systems or sensors rather than the described OTC fingertip device.

K172962	Nurture Rest	Nurture Rest (K172962) is a positioner for premature infants receiving monitored care, not an oximeter predicate.
K111007	MIDWEST REPROCESSING CENTER REPROCESSED LNCS SESSORS; MIDWES	The NMD clearance concerns reprocessed oximetry sensors, while this description concerns a reusable fingertip device and does not identify reprocessing.
K252655, K250837, K252448	Pulse Oximeter (PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, and 2 more	These DQA clearances are less suitable than the kept OTC fingertip predicates because their summaries do not establish the same OTC intended use or, for K252448, expressly state prescription use.
K241758, K222019	Reprocessed RD SET Adt Pulse Oximeter Sensor (4000); Reproc and 1 more	These NLF clearances concern reprocessed pulse oximeter sensors for continuous monitoring in hospitals and hospital-type facilities.
K172423, K160645	PediaSat Oximetry Catheter, PreSep Oligon Oximetry Catheter, and 1 more	These DQE clearances concern oximetry catheters rather than external fingertip pulse oximeters.

Adverse-event (MAUDE) and recall check

The DQA MAUDE records include reports of incorrect readings, low readings, display problems and device malfunctions, but reports are not incidence estimates and many describe bedside or neonatal use rather than OTC adult spot-checking. DQA recalls also include pulse oximeter reports involving alarms, device power cycling and display problems; those hazards merit review, but their products and use conditions are not necessarily the same as this device. **MEDIUM**

Reports are what was reported, not how often problems occur. openFDA's disclaimer applies to every number.

RECORD	TYPE	WHAT IT SAYS	CONF.
2936999-2026-00302	maude	A report describes an abnormal SpO2 and pulse reading despite stopped breathing; the relationship to the reported death was unknown.	HIGH
1282497-2026-00039	maude	A report describes a newborn for whom no valid SpO2 reading was obtained for more than ten minutes despite sensor and monitor changes, which is not the stated adult use.	HIGH
96862	recall	The recall concerns bedside SpO2 system alarms not heard or recognized, with potential treatment delay and patient harm; this device is described as having no alarms and for spot-check use.	HIGH
94170	recall	The recall reports a potential for a pulse oximeter to power off and on, resulting in loss of monitoring.	HIGH
71583	recall	The recall reports potentially missing display segments that could result in data misinterpretation.	HIGH

2 checks for this section are under What to confirm next, at the start of this report.

3. Draft substantial-equivalence table

Predicate columns are included only for kept devices with summaries in the FDA records; K211498 is the primary predicate because it is the closest OTC adult fingertip spot-check match. The user-device cells are blank where the description supplies no specification; inferred optical operation is marked as such. Comparisons refer to the primary predicate and identify differences that may need validation rather than asserting substantial equivalence.

ATTRIBUTE	YOUR DEVICE	PRIMARY PREDICATE Nonin OTC Pulse Oximeter Model 3250 K211498	PREDICATE MightySat -OTC K214115	PREDICATE YUWELL® Finger Pulse Oximeter K252805	COMPARISON	CONF.
GENERAL						
Product code and regulation	Proposed OLK; 21 CFR 870.2700.	Nonin Model 3250 OTC Pulse Oximeter; the summary describes an OTC finger pulse oximeter.	MightySat-OTC; the summary describes an OTC fingertip pulse oximeter.	DQA; 21 CFR 870.2700, Class II.	Same The proposed OLK classification is consistent with the OTC fingertip use of the primary predicate; DQA is a broader code.	HIGH
Intended use	Intermittent home spot-checking of blood oxygen and pulse rate by adults with COPD, with a doctor contacted if the reading drops.	Measures and displays functional arterial hemoglobin oxygen saturation and pulse rate for medical use without a prescription; not for diagnosis or screening of lung disease or treatment decisions.	Spot-checking of functional arterial hemoglobin oxygen saturation and pulse rate; treatment decisions should only be under healthcare-provider advice.	Reusable spot-checking device that measures and displays SpO2 and pulse rate; not suitable for continuous monitoring.	Different The COPD-specific user description and instruction to contact a doctor if readings drop are not stated in the primary predicate's indication; confirm that labeling does not add diagnosis or treatment-decision claims.	MEDIUM
Indications for use	Spot-check blood oxygen and pulse rate at home; the user contacts a doctor if the reading drops.	Spot-checking of adults 18 years and older under no-motion conditions; not intended for diagnosis or screening of lung disease or treatment decisions.	Spot-checking of individuals 18 years and older under no-motion conditions; not intended for diagnosis or screening of lung disease.	Spot-checking of adults and children weighing more than 30 kg in professional and home settings; unsuitable for continuous monitoring, motion or low perfusion.	Different The user's description adds COPD as the user population and a doctor-contact action, so the intended labeling and risk communication require review.	MEDIUM
Patient population	Adults with COPD.	Individuals 18 years and older.	Individuals 18 years and older.	Adults and children weighing more than 30 kg.	Different Adults with COPD are a narrower population than the primary predicate's adult population; confirm that performance evidence supports the intended population.	HIGH

Use environment	Home.	Spot-checking for medical use; home healthcare requirements are reported in testing.	The stated indication specifies spot-checking but does not specify a use environment in the excerpt.	Professional and home settings.	Same The stated home setting is consistent with the primary predicate's home-healthcare testing and OTC use.	MEDIUM
Prescription or over-the-counter	Sold over the counter.	Medical use without a prescription.	Over-the-counter use.	The excerpt identifies professional and home settings but does not specify prescription status.	Same OTC status matches the primary predicate; the prescription-only K252448 is a less close comparator.	HIGH
TECHNOLOGY						
Principle of operation	Fingertip pulse oximetry; optical measurement is inferred from the described device type.	The summary describes a digit pulse oximeter with an SpO2 sensor and algorithm.	The summary describes a fingertip pulse oximeter using Masimo SET technology.	Red and infrared light and a photodetector measure SpO2; pulse rate is derived from the detected signal.	Same The described fingertip pulse oximeter use is consistent with the primary predicate, but the founder has not specified the optical architecture or algorithm.	MEDIUM
Key components	Two AAA batteries; fingertip device; other components not stated.	Battery-operated finger pulse oximeter with a sensor activated by insertion of a digit and a display; includes Bluetooth radio.	Fingertip pulse oximeter with a reusable sensor; the excerpt describes a color display.	LEDs and photodetector on opposite sides of the probe, with a display and two AAA alkaline batteries.	Not stated The user description states two AAA batteries but does not specify the sensor, display or other components.	HIGH
PERFORMANCE SPECIFICATIONS						
SpO2 display range	not stated	not found	not found	0%–100%.	Not stated The description gives no display range.	HIGH
SpO2 measurement range	not stated	not found	not found	70%–100%.	Not stated The description gives no measurement range.	HIGH
SpO2 accuracy	not stated	not found	not found	±2% for 70%–100%; no definition below 70%.	Not stated The description gives no accuracy specification.	HIGH
SpO2 resolution	not stated	not found	not found	1%.	Not stated The description gives no resolution specification.	HIGH
PR display range	not stated	not found	not found	25–250 bpm.	Not stated The description gives no pulse-rate display range.	HIGH

PR measurement range	not stated	not found	not found	25–250 bpm.	Not stated The description gives no pulse-rate measurement range.	HIGH
PR accuracy	not stated	not found	not found	±1% or ±1 bpm, whichever is greater.	Not stated The description gives no pulse-rate accuracy specification.	HIGH
PR resolution	not stated	not found	not found	1 bpm.	Not stated The description gives no pulse-rate resolution specification.	HIGH
SAFETY AND STANDARDS						
Electrical safety and EMC	not stated	The summary reports compliance with IEC 60601-1-2:2014 and home healthcare requirements under IEC 60601-1-11:2015.	not found	The summary reports IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11 testing.	Not stated No safety or EMC testing is stated for the user's device.	HIGH
Biocompatibility and patient-contact materials	not stated	The summary reports ISO 10993-1:2018.	not found	The summary reports ISO 10993-1:2018 and cytotoxicity, irritation and sensitization testing; it describes a fingertip cushion made of medical silicone gel.	Not stated The device's contact materials and biocompatibility information are not stated.	HIGH
Software	not stated	The summary reports ANSI AAMI IEC 62304:2006/A1:2016.	not found	The summary reports software verification and validation and Basic Documentation Level.	Not stated The description does not state whether software is present or provide software documentation.	HIGH
FEATURES AND DESIGN						
Power	Two AAA batteries.	Battery operated.	not found	Two AAA alkaline batteries.	Different The user's two-cell configuration differs from the one AAA cell stated for K252805 and K252448; this design difference may require power and battery-safety evaluation.	HIGH
Display and user interface	not stated	The device displays numerical SpO2 and pulse rate.	The excerpt describes a color display.	Displays SpO2 and pulse rate on an LED/OLED screen with a visual pulse indicator.	Not stated The description does not state display type or interface details.	HIGH

Connectivity	No app; connectivity is not otherwise stated.	Includes a Bluetooth radio.	Connectivity is not stated in the excerpt.	YX110 models can transfer data wirelessly to a mobile device; the summary describes different models.	Different The description states no app, unlike the Bluetooth-equipped K211498; the lack of connectivity does not change the described spot-check intended use.	HIGH
Sterility and reuse	Reusable.	not found	The summary describes a reusable sensor.	Non-invasive, non-sterile and reusable.	Same The described reuse is consistent with K252805's reusable device and K214115's reusable sensor; sterility is not stated for the user's device.	MEDIUM

Testing the predicates reported

What the closest cleared devices tested, from their 510(k) summaries: a starting list for your own test plan.

TEST	STANDARD	REPORTED BY	WHAT THE SUMMARIES REPORT	CONF.
SpO2 laboratory and clinical hypoxia accuracy	ISO 80601-2-61:2017	K211498	The summary reports laboratory and clinical hypoxia accuracy testing and says clinical performance testing was provided; numerical results are not included in the excerpt.	HIGH
Clinical SpO2 accuracy and usability	ISO 80601-2-61:2017	K211498	The summary says clinical accuracy testing and user usability testing were identical to testing for its reference device and describes studies used to substantiate performance across skin pigmentation.	HIGH
Home healthcare electrical safety and essential performance	IEC 60601-1-11:2015	K211498	The summary reports compliance with the home healthcare collateral standard.	HIGH
Biocompatibility	ISO 10993-1:2018	K211498, K252805	K211498 reports ISO 10993-1:2018; K252805 reports ISO 10993-1:2018 and cytotoxicity, irritation and sensitization testing.	HIGH
Electrical safety and electromagnetic compatibility	IEC 60601-1-2:2014	K211498, K252805, K252448	The summaries report EMC testing or compliance; K252448 states IEC 60601-1-2 was relied upon from K223399.	HIGH
Pulse oximeter performance bench testing	ISO 80601-2-61:2017	K252805, K252448	K252805 reports performance bench testing; K252448 reports laboratory bench testing of SpO2 and pulse-rate measurement accuracy.	HIGH
Software verification and validation	ANSI AAMI IEC 62304:2006/A1:2016	K211498, K252805	K211498 reports compliance with the software life-cycle standard; K252805 reports software verification and validation and Basic Documentation Level.	HIGH
Usability and human factors	IEC 60601-1-6:2013	K211498	The summary reports usability testing participation by users and lists the usability collateral standard.	HIGH

Wireless testing	IEC 60601-1-2:2014	K252805	The summary includes a wireless testing section; the excerpt does not give the results or specific wireless standard.	MEDIUM
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Blanks are blanks. Nothing in this table is guessed.

2 checks for this section are under What to confirm next, at the start of this report.

4. Applicable standards

These are candidate recognized standards based on the fingertip pulse oximeter, home use, battery power and predicate testing. Standards for wireless connectivity, medical-image systems, unrelated oximeter technologies and secondary batteries are not included as applicable because the description states no app or connectivity and specifies AAA batteries.

REC. NO.	STANDARD	APPLIES	WHY	CONF.
1-139	ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) — Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	yes	ISO 80601-2-61 is the pulse oximeter particular standard and is reported in the OTC predicate summaries.	HIGH
19-49	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION — Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.	Depends	IEC 60601-1 is relevant to basic safety and essential performance of the powered medical device; confirm applicability to the final design.	MEDIUM
19-36	ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] — Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]	Depends	IEC 60601-1-2 addresses EMC and is reported for pulse oximeter predicates; assess for the final device.	HIGH
19-38	IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION — Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	yes	IEC 60601-1-11 addresses home healthcare equipment, matching the stated home use.	HIGH
2-258	ISO 10993-1 Fifth edition 2018-08 — Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Depends	ISO 10993-1 is relevant if the fingertip-contacting materials require biological evaluation; patient-contact materials are not stated.	MEDIUM
2-245	ANSI AAMI ISO 10993-5:2009/(R)2014 — Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Depends	ISO 10993-5 cytotoxicity may apply depending on the risk-based biocompatibility evaluation of contact materials.	MEDIUM
2-291	ISO 10993-23 First edition 2021-01 — Biological evaluation of medical devices - Part 23: Tests for irritation	Depends	ISO 10993-23 irritation may apply depending on the risk-based evaluation of fingertip-contacting materials.	MEDIUM
2-296	ISO 10993-10 Fourth edition 2021-11 — Biological evaluation of medical devices - Part 10: Tests for skin sensitization	Depends	ISO 10993-10 skin sensitization may apply depending on the risk-based evaluation of fingertip-contacting materials.	MEDIUM
13-79	ANSI AAMI IEC 62304:2006/A1:2016 — Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	Depends	IEC 62304 is relevant if software is part of the device; the description does not state the software architecture.	MEDIUM

5-129	ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) — Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1	Depends	IEC 62366-1 is relevant to usability engineering for a lay-operated home device.	MEDIUM
5-125	ANSI AAMI ISO 14971: 2019 — Medical devices - Applications of risk management to medical devices	yes	ISO 14971 provides a risk-management framework relevant to the device's measurements and lay use.	MEDIUM
19-54	IEC 60086-5 Edition 5.0 2021-09 — Primary batteries - Part 5: Safety of batteries with aqueous electrolyte [Including: Corrigendum 1 (2022)]	Depends	IEC 60086-5 addresses safety of primary batteries with aqueous electrolyte; confirm its applicability to the specified AAA batteries.	MEDIUM
13-122	IEC 81001-5-1 Edition 1.0 2021-12 — Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle	no	IEC 81001-5-1 addresses health software and health IT security; no app or connectivity is described.	HIGH
13-134	ISO IEEE 11073-10404 Second edition 2022-12 — Health informatics - Personal health device communication - Part 10404: Device specialization - Pulse oximeter	no	ISO IEEE 11073-10404 concerns communication with personal health devices; no communication function is described.	HIGH

2 checks for this section are under **What to confirm next, at the start of this report**.

5. What must exist before you can submit or sell

A 510(k) is the proposed premarket pathway, and the list below summarizes submission and ongoing obligations supported by the supplied regulation text.

1. 510(k) submission and substantial-equivalence support HIGH

The proposed OLK pathway is 510(k); the submission should identify the device, intended use and basis for substantial equivalence and support the comparison with appropriate testing.

21 CFR 807.81 · 21 CFR 807.87 · 21 CFR 807.92 · FDA guidance: Pulse Oximeters - Premarket Notification Submissions [510(k)s]

2. Pulse oximeter performance and home-use testing HIGH

Plan performance, electrical safety, EMC, home-use and usability evidence appropriate to the final device and claims; the OTC predicate summaries report pulse oximeter accuracy and home-use testing.

FDA guidance: Pulse Oximeters - Premarket Notification Submissions [510(k)s] · Standard 1-139 · Standard 19-36 · Standard 19-38

3. A quality management system HIGH

21 CFR 820.10(a) requires a documented quality management system that complies with the applicable requirements of ISO 13485; 21 CFR 820.1(a) applies it to all finished devices.

4. Labeling HIGH

Name and place of business (21 CFR 801.1) and adequate directions for use (21 CFR 801.5). Over-the-counter devices carry a statement of identity on the principal display panel (21 CFR 801.61).

FDA guidance: Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)

5. Unique device identification HIGH

The label of every device bears a UDI (21 CFR 801.20) that meets 21 CFR 830.20; the labeler submits device data to GUDID (21 CFR 830.300).

FDA guidance: Global Unique Device Identification Database (GUDID)

6. Establishment registration and device listing HIGH

Required of anyone who manufactures or develops specifications for a device made by a second party (21 CFR 807.20), filed electronically (21 CFR 807.21) within 30 days of starting and updated annually (21 CFR 807.22).

7. Postmarket procedures in place from day one HIGH

Complaint handling feeding medical device reporting: reports to FDA within 30 calendar days of a death, serious injury or reportable malfunction ([21 CFR 803.50](#)); reports of corrections and removals ([21 CFR 806.10](#)).

FDA guidance: [Needlesticks - Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers](#)

2 checks for this section are under What to confirm next, at the start of this report.

A quality system is where this list lives. Cove QMS builds one for companies at this stage:
coveqms.com.

6. Your plan and budget

What to test, what FDA will expect in the 510(k), what to ask FDA first, and a rough budget and timeline. It builds on the equivalence table, the standards and the obligations without repeating them.

ROUGH PLANNING TOTAL

\$70K to \$167K or more

FDA fee at the small business rate \$7,163 plus testing that applies \$63K to \$160K or more.

Not in the total

- **If FDA asks for clinical data: \$250K to \$2.5M (some simple studies under \$100K).** YES in the submission list: SpO2 accuracy is shown in a controlled desaturation study in people, including people with darker skin pigmentation. **HIGH**
- **Every year after launch:** Establishment registration, \$13,785 (no small-business rate).

When the money goes out

STEP	HOW LONG	MONEY
Small business status	FDA aims to decide within 60 days; the status lasts to September 30, so apply again each fiscal year, before you pay the fee.	No fee
Pre-Submission	Written answers within 70 days of FDA accepting the request; a meeting, if you ask for one, around day 70 to 75.	Free
Testing	No public source states a lab lead time: ask each lab when you ask for its quote.	\$63K to \$160K or more
Clinical data	No public source states how long a study takes.	\$250K to \$2.5M, not in the total
Submission	FDA's user fee is due with the submission; the small business rate needs the status above.	\$7,163 FDA fee
FDA review	FDA's goal is a decision within 90 FDA days; days waiting on your answers do not count.	No fee
Clearance	You may sell once FDA decides and you have registered.	
Registration and listing	Within 30 days of starting, then every year; FDA has no small business rate for it.	\$13,785 a year

About 5 to 6 months from sending the Pre-Sub to FDA's decision, counting only the Pre-Sub and FDA's review goal, one after the other; testing, and any time FDA waits on you, come on top.

Counted: Electrical safety and EMC, biocompatibility. Applies but has no public figure, so not in the range: performance bench testing, software verification and validation, human factors; ask labs to quote. Not included: consultants and your quality system. For scale, one firm's 2024 price sheet lists \$17,500 to prepare a 510(k) or De Novo and \$5,000 for a Pre-Sub. **The sheet.**

A rough planning number from public industry ranges, not a quote.

FDA's fee and review goal are its figures for the route proposed in section 1, shown in full on page one.

Test plan

TEST	KIND	STANDARD TO TEST TO	ROUGH COST OF THE KIND	PREDICATES THAT RAN IT
SpO2 laboratory and clinical hypoxia accuracy Supports the reading a COPD patient acts on at home: SpO2 accuracy is shown in people taken down through a range of oxygen levels. HIGH	Clinical data	1-139 ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	\$250K to \$2.5M	Nonin OTC Pulse Oximeter Model 3250 K211498

Pulse oximeter performance bench testing Verifies SpO2 and pulse-rate accuracy on a simulator and the display's behaviour at the limits of the range. HIGH	Performance bench testing	1-139 ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	No public figure	YUWELL® Finger Pulse Oximeter K252805 AViTA Pulse Oximeter K252448
Electrical safety and electromagnetic compatibility A battery-powered medical electrical device is tested for basic safety and for interference in the home. HIGH	Electrical safety and EMC	19-36 ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	\$50K to \$60K	Nonin OTC Pulse Oximeter Model 3250 K211498 YUWELL® Finger Pulse Oximeter K252805 AViTA Pulse Oximeter K252448
Home healthcare electrical safety and essential performance Over-the-counter home use brings in the home healthcare collateral standard. HIGH	Electrical safety and EMC	19-38 IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	\$50K to \$60K	Nonin OTC Pulse Oximeter Model 3250 K211498
Biocompatibility The finger chamber touches intact skin at every reading, so its materials need cytotoxicity, sensitization and irritation results. HIGH	Biocompatibility	2-258 ISO 10993-1 Fifth edition 2018-08	\$13K to \$100K or more	Nonin OTC Pulse Oximeter Model 3250 K211498 YUWELL® Finger Pulse Oximeter K252805
Software verification and validation The firmware computes and displays SpO2 and pulse rate. HIGH	Software verification and validation	13-79 ANSI AAMI IEC 62304:2006/A1:2016	No public figure	Nonin OTC Pulse Oximeter Model 3250 K211498 YUWELL® Finger Pulse Oximeter K252805
Usability and human factors Lay users with COPD read the display and decide whether to call a doctor, so the use-related risks need a usability evaluation. HIGH	Human factors	5-129 ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text)	No public figure	Nonin OTC Pulse Oximeter Model 3250 K211498

Rough public industry ranges for a whole kind of testing, not a quote: a lab usually quotes a kind as one program, so the budget counts each kind once. Read on 2026-09-26. Sources are listed at the end.

- **Performance bench testing: No public figure.** No public figure: labs price bench tests one by one, so send them this test list for a quote. Medical Device Academy puts its clients' whole testing budget at around \$100K on average.
- **Electrical safety and EMC: \$50K to \$60K.** Medical Device Academy puts the total cost of this testing at typically \$50K to \$60K.
- **Biocompatibility: \$13K to \$100K or more.** About \$13K for a non-invasive device, up to \$100K or more for a long-term implant's implantation studies.
- **Software verification and validation: No public figure.** No public figure: the work is mostly your team's. FDA's documentation level, Basic or Enhanced, sets how much you write; Medical Device Academy says the documentation typically runs 300 to 1,000 pages.
- **Human factors: No public figure.** No public figure. FDA recommends at least 15 participants from each distinct user group in the summative (validation) test.
- **Clinical data: \$250K to \$2.5M.** A human clinical study runs \$250K to \$2.5 million, and about one 510(k) in ten needs one; some simple studies, such as for infrared thermometers, cost under \$100K and resemble bench testing.

What the submission will contain

PART	APPLIES	WHY
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Device description and intended use	YES	Every 510(k) describes the device and its intended use: intermittent home spot checks by adults with COPD. HIGH
Indications for use	YES	The indications must state over-the-counter adult spot-check use at home, as OLK clearances such as K211498 do. HIGH
Substantial-equivalence comparison	YES	The 510(k) compares the device with the kept predicates, as the equivalence table in section 3 lays out. HIGH
Labeling	YES	Over-the-counter labeling must let a lay user act on a low reading safely, including when to contact a doctor. HIGH
Performance bench testing	YES	SpO2 and pulse-rate accuracy on a simulator and display behaviour are verified before the clinical study. HIGH
Electrical safety and EMC	YES	A battery-powered device used at home is tested to 19-49, 19-36 and the home healthcare standard 19-38. HIGH
Biocompatibility	YES	The finger chamber contacts intact skin at every use. HIGH
Sterility and shelf life	NO	A reusable device on intact skin is not sold sterile, and no shelf-life claim is stated. MEDIUM
Software documentation	YES	Firmware computes the readings; Basic documentation level fits, since a failure gives a wrong reading that the labeling tells the user to confirm, and K252805 reports Basic. MEDIUM
Cybersecurity	NO	The description rules out an app and any connection, so the device is not a cyber device. MEDIUM
Human factors	YES	Lay users acting on a reading at home make use errors a critical task, and K211498 reports usability testing with users. MEDIUM
Clinical data	YES	SpO2 accuracy is shown in a controlled desaturation study in people, including people with darker skin pigmentation. HIGH

Questions for a Pre-Submission

A Pre-Submission is free: FDA charges no fee. FDA answers in writing within 70 days of accepting the request and, if you ask for a meeting, meets you around day 70 to 75. [FDA's Q-Submission guidance](#).

1. Is K211498, an over-the-counter oximeter, the right primary predicate for a device aimed at adults with COPD, or does naming COPD in the indications raise a new question of safety or effectiveness?

MEDIUM

A disease-specific indication at home is the claim closest to the edge of OLK.

2. How many participants with darker skin pigmentation does FDA expect in the desaturation study, and does it accept testing to the recognized edition of ISO 80601-2-61 (1-139) alone?

MEDIUM

The clinical accuracy study is the largest cost and the longest lead time in the plan.

3. Is a summative usability test with lay users with COPD expected, or does labeling comprehension testing cover the decision to contact a doctor?

LOW

The answer decides whether a human factors study with at least 15 users is in the budget.

4. Does FDA agree that the home healthcare standard 19-38 applies with 19-49, and which edition of IEC 60601-1-2 (19-36) it expects?

MEDIUM

The predicates reported older editions than the ones recognized now.

Where the money can come from

Public programs to check, not advice: Cove has no part in them, and each program decides who qualifies. Pediatric programs appear when the description mentions children, defense programs when it mentions military use. Read on 2026-09-26. Other states run similar matching programs; your state's economic development office will know.

PROGRAM	TYPICAL AWARD
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NIH SBIR and STTR Research and development grants from the National Institutes of Health to US small businesses, medical devices among them.	Phase I about \$323,090 over 6 months to 2 years; Phase II about \$2,153,927 over 1 to 3 years; some topics allow more by waiver.
NSF SBIR and STTR (America's Seed Fund) National Science Foundation grants for startups in most technology areas, medical devices included; you keep full ownership of the company and its IP.	Phase I up to \$305,000; Phase II up to \$1,250,000 over 24 months.
ARPA-H SBIR and STTR Small business awards from the Advanced Research Projects Agency for Health on set topics, open for a limited time (the 2026 topics close in September and October 2026).	Phase I up to \$600,000; Phase II up to \$3.5 million.
MedTech Innovator An accelerator for medical device, diagnostic and digital health companies that have raised up to a Series C, with mentors from its corporate partners.	Early-stage (pre-Series B) companies compete for up to \$500,000 in funding (2026 cohort).
Kentucky SBIR/STTR Matching Funds (state) Matches a federal SBIR or STTR award for a for-profit company based in Kentucky or willing to move there.	Up to \$100,000 for Phase I and up to \$150,000 for Phase II.
Kansas SBIR/STTR Matching Program (state) Helps a small business headquartered in Kansas prepare a federal SBIR or STTR proposal and matches a Phase I award.	Up to \$3,000 for proposal development (a 50% match); up to \$25,000 to match a Phase I award.

2 checks for this section are under **What to confirm next, at the start of this report**.

Sources

Every claim in this report comes from these public FDA sources; web search was not a source. The report reads a dated copy of each; the links go to the live versions. A second model read the records and the draft before it was sent.

- [FDA product classification database](#)
- [FDA 510\(k\) premarket notification database](#)
- [FDA recognized consensus standards database](#) · copy of 2026-09-13
- [eCFR, Title 21, Chapter I, Subchapter H \(medical devices\)](#) · copy of 2026-09-01
- [FDA medical device recalls database](#)
- [FDA MAUDE adverse event database](#)
- [FDA guidance documents](#)
- [openFDA downloads](#) · openFDA export 2026-09-07

Planning figures in section 6

The rough costs and timings in section 6 are not FDA records about the device: they are public figures, added the same way to every report, each with the day it was read.

- [Medical Device Academy, How much does a 510k cost? \(Rob Packard, 2021\)](#) · read 2026-09-26
- [Medical Device Academy, standard pricing sheet \(April 21, 2024\)](#) · read 2026-09-26
- [FDA guidance: Requests for Feedback and Meetings for Medical Device Submissions, the Q-Submission Program \(May 29, 2025\)](#) · read 2026-09-26
- [FDA guidance: Applying Human Factors and Usability Engineering to Medical Devices \(August 3, 2026\)](#) · read 2026-09-26
- [FDA user fees for FY2027 \(Federal Register, July 30, 2026\)](#) · read 2026-09-24
- [MDUFA V performance goals](#) · read 2026-09-24
- [FDA small business program](#) · read 2026-09-24

Funding programs in section 6

The programs this report lists, each from its own public page.

- [NIH SBIR and STTR](#) · read 2026-09-26
- [NSF SBIR and STTR \(America's Seed Fund\)](#) · read 2026-09-26
- [ARPA-H SBIR and STTR](#) · read 2026-09-26
- [MedTech Innovator](#) · read 2026-09-26
- [Kentucky SBIR/STTR Matching Funds](#) · read 2026-09-26
- [Kansas SBIR/STTR Matching Program](#) · read 2026-09-26

What the records could not tell us

- The complete K211498 and K214115 summaries are not reproduced in the excerpts, and the full testing details for the kept predicates should be reviewed before submission planning.
- The supplied regulation excerpt for 21 CFR 870.2700 gives device identification and Class II classification but not the full performance-standard text; the applicable standard and submission expectations should be confirmed.