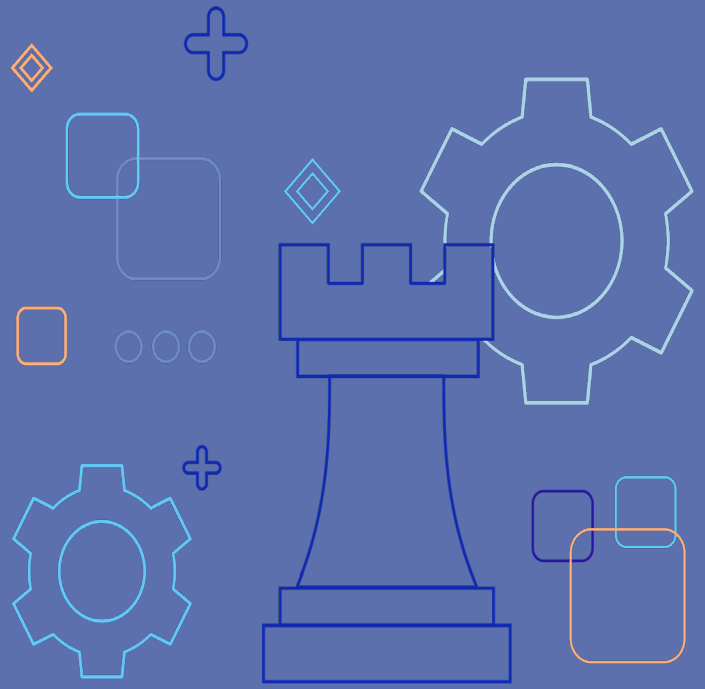
ROOK QUALITY SYSTEMS

Navigating FDA Submissions for Wearables & Home-Use Devices



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60-Minute Webinar

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Speaker Introductions

Tyler Ting, MS, RAC

Regulatory Director
Rook Quality Systems

- → 10+ years of serving as a regulatory consultant for medical device companies around the world
- → Multiple successful 510(k) submissions and FDA interactions
- → Emergency Use Authorization of COVID-19 IVD
- → Education in Mechanical Engineering and Biochemistry

ROOK QUALITY SYSTEMS

About Rook Quality Systems

Rook Quality Systems specializes in assisting medical device companies, from startups to Fortune 500 firms, in developing and maintaining robust quality systems.

Our customized consulting services cater to all classes of medical devices, including medical software and combination devices, ensuring regulatory compliance and operational excellence.

ROOK QUALITY SYSTEMS

Our Core Values

Patient First Mentality

Our #1 priority is ensuring quality through compliance so that innovative and safe medical devices get to patients and users efficiently.

Proactive, Not Reactive

From designing long-standing quality systems to staying ahead of the ever-changing regulatory landscape, we approach each project with proactive and dynamic solutions.

High-Tech, High-Touch

Leveraging relevant technology is essential to achieving optimal results for our clients and ultimately improved outcomes for patients.

Why This Matters for You

6–18 Months Delays

Delay risk from a poorly planned submission — that's runway, investor conversations, and market window.

Exploding Market Opportunity

cardiac patches, home monitors, wellness wearables — all growing fast. FDA expectations are keeping pace.

Prevent Common Mistakes

The biggest delays come from not knowing the rules of the game early enough. That's what today is for.

Agenda

Our Agenda
For Today

FDA Submission for Wearables & Home-Use Devices

60-Minute Webinar

1. **Choosing Your FDA Pathway**
   General Wellness, 510(k), De Novo, or PMA
2. **Documentation Requirements**
   Key sections and common gaps that delay submissions
3. **Human Factors & Usability**
   What the FDA expects for home-use devices
4. **Cybersecurity & Software**
   Connected devices, SaMD, and AI/ML
5. **Responding to the FDA**
   Handling requests and keeping on track

The FDA Pathway Landscape

Four pathways — matched to your device's risk level and novelty

General Wellness

No submission required

Low-risk products with general health claims only — no diagnosis, treatment, or prevention.

Low Risk

510(k) Exempt

Establishment Registration

Devices subject to General Controls. No requirement to seek FDA authorization but must comply with QMSR

Moderate

510(k)

Premarket Notification

Prove substantial equivalence to a legally marketed predicate. Most common wearable pathway.

Novel/Moderate

De Novo

Novel Classification

No predicate exists. Establish a new device class. You become the predicate for future 510(k)s.

High Risk

← Low complexity / risk

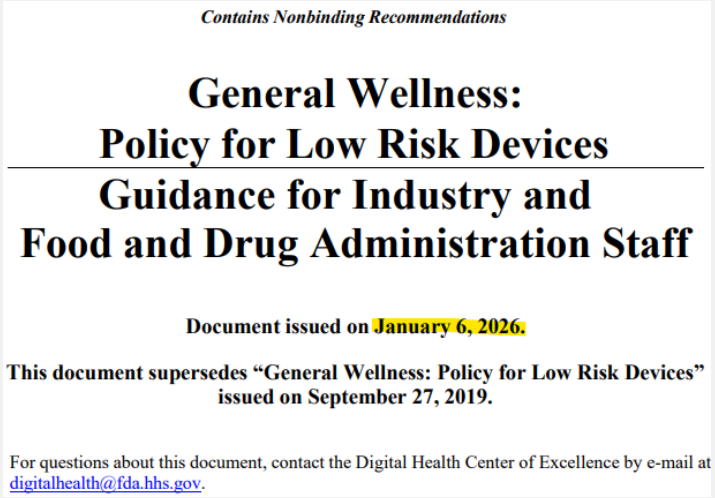
High complexity / risk →

Pathway 1: General Wellness

What counts as General Wellness:

Low-risk products making general health claims — not diagnosing, treating, or preventing a disease.

- Step counters and activity trackers
- Sleep tracking apps
- Stress management / mindfulness apps
- Calorie counters and general fitness tools



Contains Nonbinding Recommendations

General Wellness:
Policy for Low Risk Devices

Guidance for Industry and
Food and Drug Administration Staff

Document issued on January 6, 2026.

This document supersedes "General Wellness: Policy for Low Risk Devices" issued on September 27, 2019.

For questions about this document, contact the Digital Health Center of Excellence by e-mail at digitalhealth@fda.hhs.gov.

No Submission

No FDA filing required

⚠ The Claims Test

Write down every claim in your marketing, app, and packaging.

Ask: "Does this claim diagnose, treat, mitigate, or prevent a disease?"

If yes → you are NOT a General Wellness device. Full stop.

Pathway 2: 510(k) Exempt

When an exemption applies: Find your device's generic classification

"Exempt" does not mean unregulated. Register your facility, list your device, and meet general controls — skip the premarket notification.

- Product code determines eligibility — search the FDA 510(k) Exempt product code database before assuming your device qualifies. Exemptions are product-code-specific.
- General controls still apply: proper labeling, Quality System Regulation (21 CFR Part 820/QMSR), and Good Manufacturing Practices. Compliance is required even without a 510(k).

1 to 10 of 1000 results *
Device Class 1

1 2 3 4 5 6 7 8 9 10 >

Results per page 10

New Search

Export to Excel Help

Product Code	Device		Regulation Number	Device Class
BRW	Protector, Dental	Dental Protector	868.5820	1
BRX	Stool, Anesthesia	Anesthesia Stool	868.6700	1
BRY	Cabinet, Table And Tray, Anesthesia	Anesthetic Cabinet, Table, Or Tray	868.6100	1
BSF	Absorber, Carbon-Dioxide	Carbon Dioxide Absorber	868.5310	1
BSJ	Mask, Gas, Anesthetic	Anesthetic Gas Mask	868.5550	1
BSR	Stylet, Tracheal Tube	Tracheal Tube Stylet	868.5790	1
BSY	Catheters, Suction, Tracheobronchial	Tracheobronchial Suction Catheter	868.6810	1
BTB	Hook, Ether	Ether Hook	868.5420	1
BTC	Bag, Reservoir	Reservoir Bag	868.5320	1
BTK	Strap, Head, Gas Mask	Gas Mask Head Strap	868.5560	1

* The maximum **1000** devices meeting your search criteria returned. Please narrow your search.

No Submission
Required
QMSR
Required

Low
Risk Tier

Red Light Therapy, Cognitive Assessments, Rehabilitative Equipment

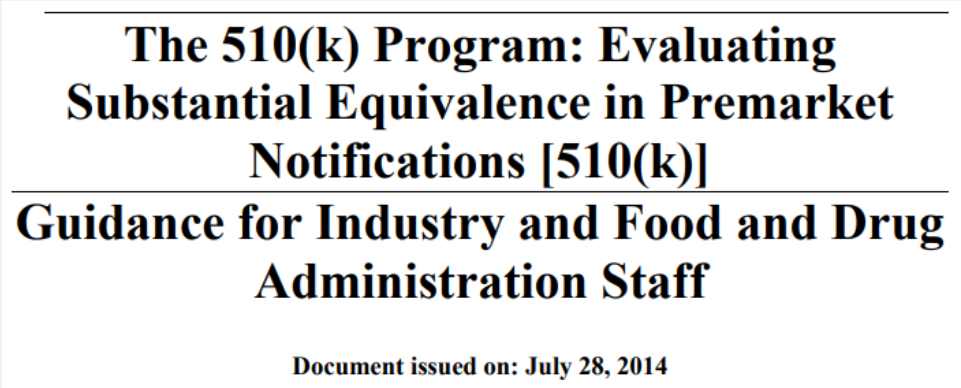
Confirm your product code before assuming exemption applies.

Pathway 3: 510(k) — Premarket Notification

The substantial equivalence argument:

"My device is substantially equivalent to a legally marketed predicate device." = same intended use, differences in technology addressed through testing

- Predicate Selection: Find a cleared device with the same intended use & technology. Search FDA's 510(k) database. The wrong predicate breaks your whole argument.
- Substantial Equivalence Argument: The heart of your submission. Make it tight, logical, and fully supported by test data. Walk the reviewer through it.



The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

Document issued on: July 28, 2014

Submission Length
6–12 Months
officially 90 days

Most Common Wearable Pathway

Blood glucose monitoring, ECG patches, pulse oximetry — predicates exist for most categories.

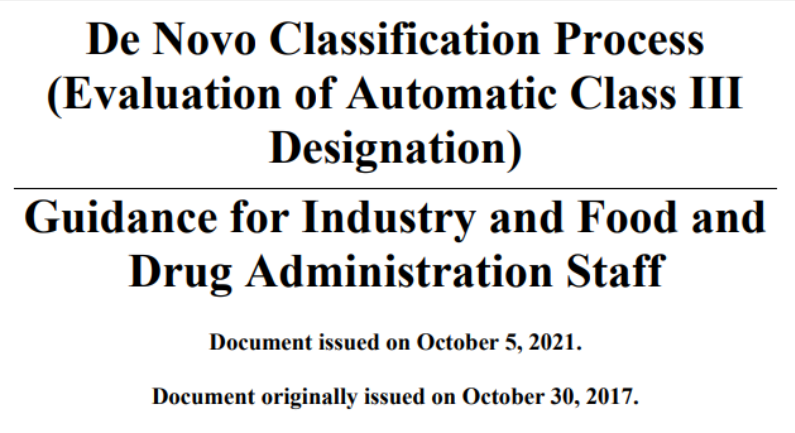
The most commonly used pathway for wearable startups.

Pathway 4: De Novo

When to use De Novo:

Your device is genuinely novel — no predicate exists. De Novo lets you establish a new device classification.

- More extensive safety and effectiveness data required than 510(k)
- If cleared, your device becomes a predicate for future 510(k)s
- Best for: AI diagnostics, next-gen biosensors, multi-parameter home monitors



De Novo Classification Process (Evaluation of Automatic Class III Designation)

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 5, 2021.

Document originally issued on October 30, 2017.

12+ Months

longer than 510(k)

You Become the Predicate

Once cleared, future 510(k) submissions can cite your device as their predicate.

You're not just getting cleared — you're creating a new device category.

Documentation Requirements

Your regulatory submission is the complete story of your device.

Device Description

Precise specs, diagrams, components, materials. Include software if present.

Intended Use & Indications

What it does, who it's for, under what conditions. Anchors your whole submission.

Human Factors

Use related errors mitigated through adequate design and testing. Especially important for OTC devices available through online retailers.

Verification & Validation

Performance testing that mirrors actual use — non-trained users, home environment.

Labeling

Packaging, IFU, app UI. Plain language required for home-use.

Software Documentation

Cybersecurity, Software Development Practices, Software Requirements and Testing. Not an afterthought.

5 Common Submission Gaps

These are the issues that generate Additional Information requests and blow your timeline.

01

Predicate comparison isn't tight enough

Logical holes in your substantial equivalence argument. Stress-test it before filing.

02

Performance testing doesn't match intended use

Validated in a clinical lab when your device is for home use by untrained users.

03

Software documentation is incomplete

Missing SDLC, incomplete V&V, no known anomalies list.

04

Human factors data is missing or underpowered

Not identifying critical tasks from formative studies, or summative study with wrong user population.

05

Labeling not tested with real users

Your IFU makes sense to you — but customers can't follow it. User-test your labeling.

Usability Engineering & Human Factors

FDA's core question: "Can a real, non-expert user use this device correctly and safely in a real home environment?"

STEP 1

Use-Related Risk Analysis

Identify critical tasks users must perform correctly. Assess consequences of failure — what are the use errors and their impact?

STEP 2

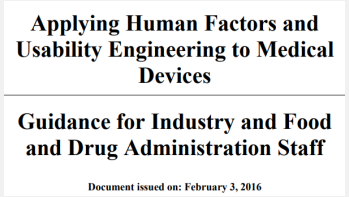
Formative Studies

Watch real users during development. Identify stumble points. Feed findings back into design iteratively — run these early and often.

STEP 3

Summative Validation

Final design, representative user population. FDA wants acceptable rates of correct critical task performance on your final device.


Applying Human Factors and Usability Engineering to Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

Cybersecurity & Software Documentation

If your device connects to anything or runs an algorithm — this section is for you.

CYBERSECURITY

- Cybersecurity management plan required in your submission
- Threat modeling — identify all attack vectors
- Security controls: encryption, authentication, access
- Software Bill of Materials (SBOM) — every third-party component, including open-source
- Post-market patch and update plan

SOFTWARE / SaMD

- Software Development Lifecycle (SDLC) document
- Architecture diagrams
- Software Requirements Specification (SRS)
- V&V test protocols and results
- List of known anomalies
- AI/ML: training data, model validation, update strategy post-clearance

Pre-Submission Meetings (Q-Sub)

An underused tool that can save months of rework — before the clock even starts.

HOW IT WORKS

- Submit a formal Q-Sub request to FDA before filing
- Include your device overview, proposed pathway, and testing plan
- Ask specific, direct questions
- FDA responds in writing within 90 days
- Feedback is directional — not binding, but it matters

WHY IT'S WORTH THE WAIT

- Confirm your predicate strategy before committing
- Validate your testing plan before running expensive studies
- Catch labeling or intended use issues early
- Avoid AI requests after submission — before the clock starts

Responding to FDA Additional Information Requests

Most submissions get at least one. How you respond determines your timeline.

Read every question carefully

Answer the question they asked — not the one you expected. Misreading buys you another round.

Respond comprehensively

Don't give minimal answers. Data plus context. Give them everything they need to say yes.

Organize clearly

Number responses to match their questions. Use headers. Make it easy for the reviewer.

Be direct about any changes

If you're updating something, say so clearly. Summarize the change. Don't bury it.

Don't argue — come with data

Note your position respectfully, backed by data. The goal is clearance, not debate.

Keeping Your Submission On Track

Assign a single FDA point of contact

All communication flows through one person. Multiple people emailing different reviewers creates confusion.

Track every communication

Log every email, meeting, question and answer. When responding to an AI request 6 months in, you'll need it.

Front-load your documentation

Build your technical file alongside development — risk analysis as you design, V&V as you finalize specs.

Know your reviewer's clock

Once accepted, follow the timeline. If approaching the end without feedback, it's okay to follow up.

Budget for iteration

Almost no submission sails through on the first pass. Budget time and money for at least one AI response round.

5 Things to Walk Away With

01 Know your pathway early. Don't assume General Wellness or 510(k). Do your classification homework before you're deep in development.

02 Your documentation strategy IS your development strategy. Build your technical and regulatory documents alongside your device.

03 Human factors is not optional for home-use devices. Start your usability program early. Your users are not engineers.

04 Software and cybersecurity expectations are only going up. Treat them as first-class deliverables, not afterthoughts.

05 Use the tools the FDA gives you. Pre-submission meetings, interactive review — the FDA wants you to succeed.

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Questions?

Let's dig into your device, your pathway questions, or anything from today's session.

info@rookqs.com | www.rookqs.com