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Wearable Health Labels: Cleared, Certified or Wellness

Three health wearables made news in five weeks under three different labels, and each label answers a different question about what anyone checked

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Three labels in five weeks

FDA clearance, ISO 13485 certification and a general-wellness label sound alike in a headline. They say very different things about a device, and each answers its own question. Clearance means the US Food and Drug Administration reviewed one device for one stated use. Certification to ISO 13485, an international quality standard, means an auditor checked a company's processes and says nothing about any product at all. A wellness label means nobody at FDA looked. Between early September and mid-October 2026, three wearables carried one label each.

- On 3 September 2026 FDA cleared Happy Health's "Happy Health Blood Pressure Monitor," a ring, under 510(k) number K254000. The trade press called it cuffless, with no calibration step.
- On 7 October 2026 Oura announced that its quality management system for medical-device software is certified to ISO 13485.
- In October 2026 Google launched the Fitbit Edge tracker. Its Health Guardian feature shows blood pressure and insulin-resistance trends. Google's footnote says they're "intended for general wellness and informational purposes only."

All three touch blood pressure or medical software. Coverage blurred them. A regulator reviewed one of them, and only for what its maker claimed.

Intended use decides the route

Under US law a product is a medical device mostly because of its intended use, which is what the maker says it's for. A ring that gives you a sleep score is one thing. The same ring is another once its maker says it detects hypertension.

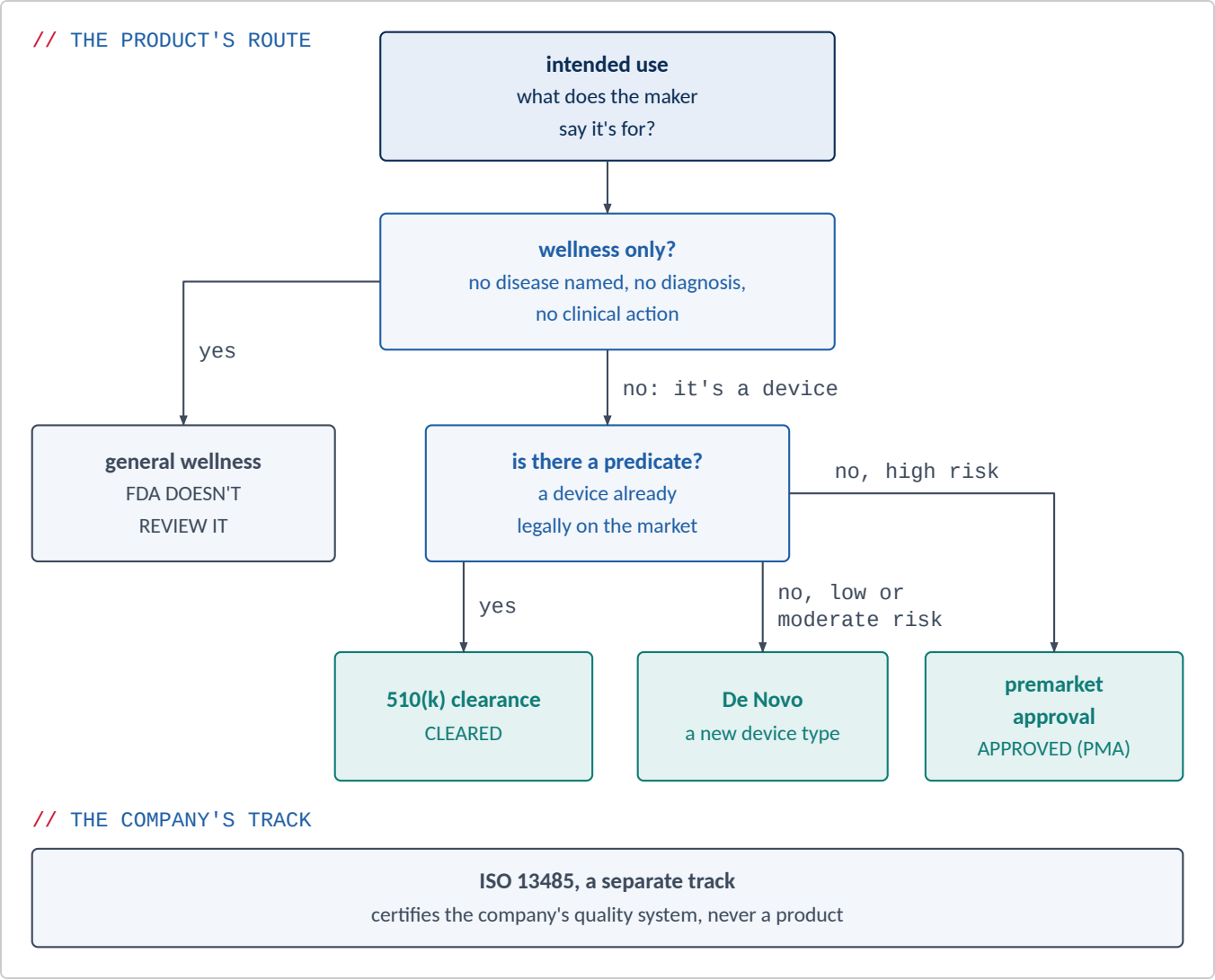


Figure 1. Follow the maker's claim down the page: a wellness-only claim stops at the left, and every device claim ends in one of three FDA routes.

The claim sets the route, and the route sets what a reader can trust. A label is a short answer to the question of who checked what, and each one below answers it

differently.

General wellness: nobody at FDA reviewed it

FDA's general-wellness policy covers low-risk products meant only to maintain or encourage a healthy lifestyle. FDA revised it in January 2026, and the revision changed blood pressure. Covington & Burling, the law firm, read it as reversing FDA's 2025 position that products estimating blood pressure are devices. A non-invasive wearable that outputs blood pressure can now be a wellness product if its use stays strictly about wellness.

The conditions carry the weight. Covington lists five things that push a product out of the wellness category:

- values that "mimic those used clinically," unless validated;
- claims of clinical equivalence or "medical grade";
- prompting a specific clinical action;
- measuring for screening, diagnosis or monitoring;
- naming diseases or diagnostic thresholds.

A wellness product may say that "evaluation by a healthcare professional may be helpful." Calling a reading abnormal is off limits.

Google's wording for Fitbit Edge follows that line closely. The footnote says the trends aren't a prescreener for hypertension or diabetes, don't give real-time clinical readings, and shouldn't be used to adjust medication. That's a wellness label working as designed — FDA hasn't reviewed the feature, and Google doesn't claim it has.

510(k) clearance: reviewed against a predicate

A 510(k) is a premarket notification, named for the section of the law that requires it. The maker shows FDA that its device is "substantially equivalent" to one already legally on the market, which is called the predicate. Under 21 CFR 807.100 that means the same intended use. It also means the same technology, or evidence that a

different technology is as safe and effective and raises no new questions. If FDA agrees, the device is cleared. That's the whole test.

Happy Health's K254000 is that kind of decision: FDA reviewed this device, for its stated use, against a predicate. That's narrower than it sounds. High-risk devices and drugs get approval, a heavier review. A clearance also covers only the indications in the decision, so a feature on the ring outside them is uncovered.

The decision summary wasn't available when I looked, so the accuracy data FDA saw and the exact indications it cleared are both unknown here, and anyone quoting a number for this ring's accuracy is quoting the company.

The standard for this kind of device is still moving. On 23 January 2026 FDA published draft guidance on testing cuffless blood pressure devices, with comments due by 24 March. FDA says the draft is "not for implementation at this time."

De Novo and premarket approval

A new device with no predicate takes one of two other routes. A low- or moderate-risk device can go through De Novo (21 CFR 860.200). That creates a new device type, which later devices can use as their predicate. A high-risk device goes through premarket approval (PMA) and needs its own evidence of safety and effectiveness. Neither route applies to the three products in the news.

ISO 13485: a certificate for the company

ISO 13485:2016 is titled "Medical devices — Quality management systems — Requirements for regulatory purposes." It sets out how a company designs, makes and tracks medical devices. That means documented processes, design controls, supplier control, complaint handling and corrective action. Accredited certification bodies audit a company and issue the certificate. FDA's quality rule, 21 CFR 820.7, now incorporates the standard by reference; a company heading toward FDA needs it anyway.

Oura's announcement is careful on exactly this point. The certificate covers its quality system for "the development, production, and distribution of medical device

software” for digital health applications. In the release’s own words it ”does not apply to any specific Oura software, hardware, or general wellness features.” It’s also described as something other than clearance or approval, and outside its regulated features the Oura Ring ”is not a medical device.”

What the certificate shows is machinery. A company builds it before asking for clearances, and Oura calls it a base for evaluating regulatory routes in the United States and elsewhere. The certifying body goes unnamed.

Reading the label

Side by side, the three products answer three different questions.

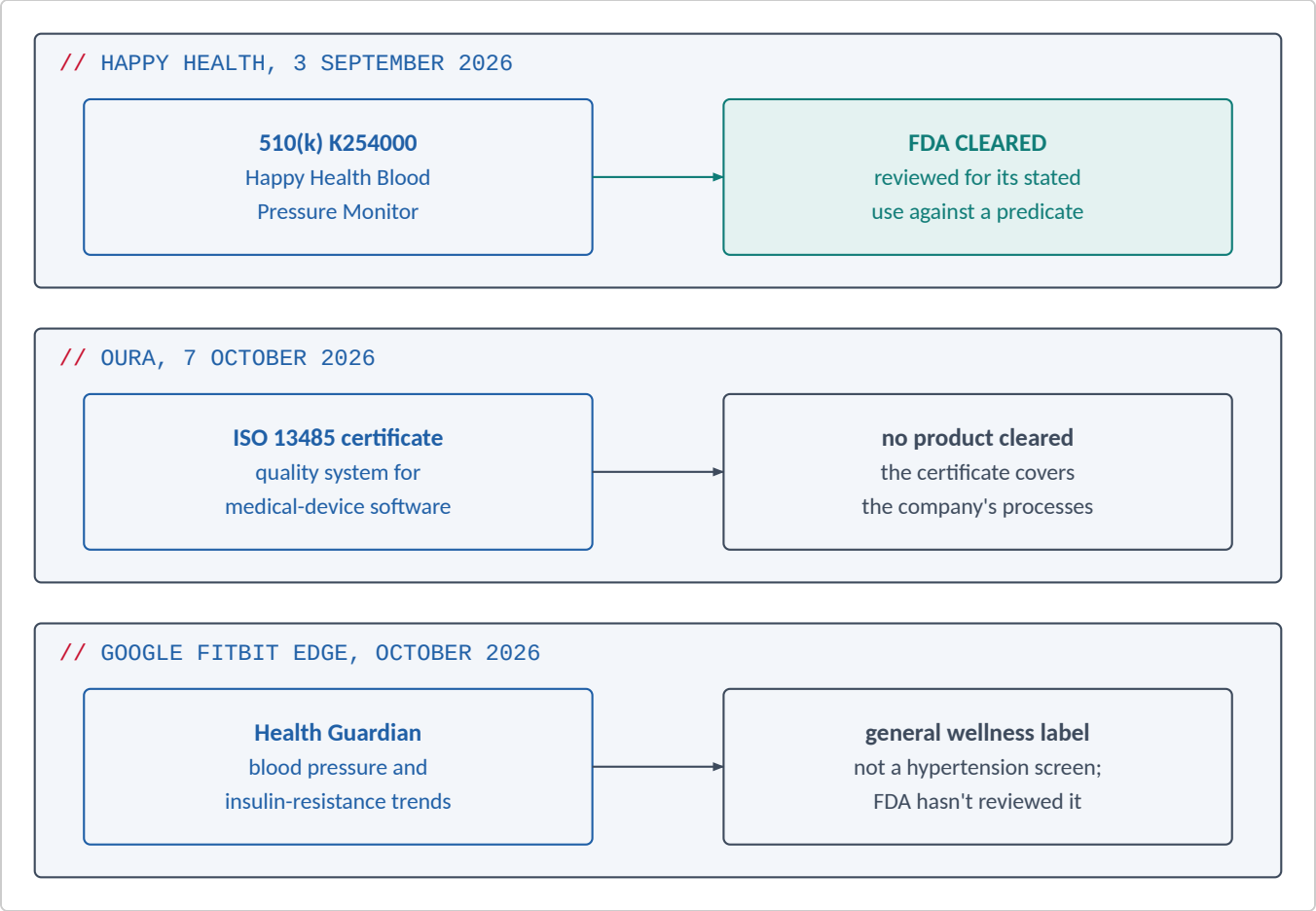


Figure 2. Each row is one product and one label; only the top row records a review of a device by FDA.

Four phrases turn up in health-device news, and each has a plain reading.

1. ”FDA cleared” means FDA reviewed a claim. Look up the 510(k) number, because the indication in it is the claim FDA reviewed.
2. ”ISO 13485 certified” means an auditor checked the company’s processes. It says nothing about whether a particular product works.
3. ”For general wellness” means FDA didn’t review it and the maker isn’t claiming it diagnoses anything.
4. ”Medical grade” or ”clinically accurate” with no clearance number is a claim the 2026 wellness policy says a wellness product shouldn’t make.

What isn't known

Three gaps stay open. The accuracy figures and exact indications behind K254000 haven’t been published in a form I could read. Oura hasn’t named its certification body or the full scope beyond the press release. And nobody yet knows how FDA will apply the January 2026 revision in practice; Covington notes that it leaves ambiguities.

Why it matters

Patients bring these readings to clinics, and soon they’ll bring them to clinical AI. MARA, the Medical Agentic Resident Assistant this project is designing, will read data from rings and watches alongside the record. A cleared measurement and a wellness trend may show the same number on the same screen. They carry different weight, and MARA has to say which is which every time she reports one. A blood pressure trend labelled wellness is context for a clinician, never a reading to act on. Her design for records the patient brings already carries that rule; the build hasn’t started.

The same discipline applies to anyone reading the news. When a headline says a wearable ”measures blood pressure,” ask who checked the claim. The label usually answers in one word.

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- 21 CFR 807.100 (substantial equivalence), 21 CFR 860.200 (De Novo) and 21 CFR 820.7 (ISO 13485:2016 incorporated by reference), via the Legal Information Institute.

Glossary

TERM	DEFINITION
510(k)	a premarket notification showing that a device is substantially equivalent to one already on the market. FDA "clears" a device on that basis, and the clearance covers only the stated indications.
CFR (Code of Federal Regulations)	the compiled US federal rules. Title 21 holds FDA's, including the device routes cited here.
Cuffless blood pressure	an estimate of blood pressure from sensor signals without an inflating cuff. FDA's January 2026 draft guidance covers how such devices should be tested.
De Novo	FDA's route for classifying a new low- to moderate-risk device type that has no predicate. The new type can then serve as a predicate for later devices.
FDA (US Food and Drug Administration)	the federal agency that regulates medical devices. Its review is what "cleared" refers to.
General wellness product	a low-risk product meant only to support a healthy lifestyle. FDA doesn't review it, which is why its readings count as context rather than measurements.
Indication	the specific use a clearance covers. A feature outside it isn't covered by the clearance.
Intended use	what the maker says a product is for. It largely decides whether the product is a device and which route it takes.
ISO 13485	the international standard for medical-device quality management systems. Companies are certified to it; products aren't.

TERM	DEFINITION
MARA (Medical Agentic Resident Assistant)	this project's design for a clinical assistant that recommends while a person decides. She'll have to weigh cleared and wellness readings differently.
PMA (premarket approval)	FDA's route for high-risk devices, which needs the device's own evidence of safety and effectiveness.
Predicate	the legally marketed device a new one is compared with in a 510(k).
Quality management system	the documented processes a company uses to design, make and track products. ISO 13485 certifies one.
Substantial equivalence	the 510(k) test: the same intended use, and the same technology or evidence that different technology is as safe and effective.

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// ABOUT THE AUTHOR

Jason Newell leads organizations and people in technology, and is a researcher, deep technologist and builder — from a CRAY to agentic AI. He founded MAX Research Collective to build AI for regulated industries that runs where its owner has control, with healthcare as its strongest focus. About Jason → Connect on LinkedIn →

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