



WHOOOP There It Goes: Wellness Has a New Avenue for Trend Tracking Minus Device-Type Claims

On June 17, 2026, the U.S. Food and Drug Administration (FDA) issued a [closeout letter](#) to WHOOP, Inc. dropping enforcement action against its Blood Pressure Insights (BPI) feature after WHOOP updated the product and its labeling to align with the FDA's revised [January 2026 General Wellness: Policy for Low Risk Devices](#) guidance, which replaced its 2019 guidance.

What was the fuss about? On July 14, 2025, FDA sent WHOOP a [warning letter](#), where FDA described WHOOP's product, BPI as "adulterated" and "misbranded" because WHOOP did not notify FDA of its intent to introduce the product into commercial distribution and did not have an approved application for premarket approval (PMA). FDA indicated that it had met with WHOOP and disagreed with WHOOP's position that its product was a wellness device and only provided a daily estimation of a subject's blood pressure and was "not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease."

FDA cited the following support for its position:

- BPI is intended to measure or estimate a user's blood pressure, which is inherently associated with a diagnosis of hyper- or hypotension – a diagnosis of disease.
- BPI uses green, yellow, and orange color coding to indicate target ranges.
- Neither BPI's disclaimers nor its midpoint measurement (versus real-time measurement) changes its intent to provide a blood pressure estimation inherently associated with a diagnosis of a disease or condition (i.e., hyper- or hypotension).

- BPI includes statements about how poor sleep may be associated with high blood pressure, and blood pressure is purportedly measured by BPI.
- Blood pressure is typically measured in a health care setting, and providing even an estimation of blood pressure is “not a low-risk function.”
- FDA actively regulates devices to measure blood pressure under 21 C.F.R. § 870.1130, and inaccurate readings could lead a user to think they have normal blood pressure and not seek treatment that might prevent a stroke, heart attack, heart failure, kidney failure, cognitive decline, or premature death.

In response to FDA’s warning letter to WHOOP, Founder and Chief Executive Officer Will Ahmed posted a LinkedIn [response](#) where he disagreed with FDA’s conclusion, noting that blood pressure estimations should be treated like heart rate and respiratory wearables. Ahmed said WHOOP has “gone above and beyond” to have BPI support healthy lifestyles, noting that it tells consumers it is not a medical device, does not diagnose hypertension or another disease, accurately estimates blood pressure based on passive overnight trends, and requires members to proactively acknowledge BPI is not a “medical feature.” Ahmed also reportedly petitioned U.S. Secretary of Health and Human Services Robert F. Kennedy Jr. to adjust FDA’s thinking.

Some commentators [thought](#) that FDA had gone too far in its warning letter, believing FDA’s “inherent association” of blood pressure measurement with a diagnosis of hypertension or hypotension was a “stretch.” In addition, FDA’s objection to the color scheme was cited as also not supported in the world of wearables for wellness where such colors are often used without the association to a clinical diagnosis. Some commentators also thought FDA’s connection to higher blood pressure and sleep did not reach the level FDA suggested that “higher blood pressure” necessarily meant the BPI was intended for patients with “high blood pressure.” At the same time, the commentators thought WHOOP could have resolved at least several issues cited in the warning letter by simply adjusting the color scheme or not using a traditional cuff measurement of blood pressure to calibrate BPI, which suggested parallels with a medical device type of regulation.

FDA’s new wearable guidance explicitly permits noninvasive wearables to output estimated physiological parameters – such as blood pressure – provided they do not prompt clinical intervention or claim medical-device status. WHOOP’s further

adjusted BPI as follows to obtain its closeout letter:

- **Removal of “Medical-Grade” Claims:** WHOOP eliminated promotional and labeling language implying “clinical equivalence, clinical accuracy, or medical-grade” performance of BPI.
- **Shift to Continuous Color Gradients:** The user interface replaced discrete, clinical-style color-coded cutoffs (red / yellow / green zones mimicking clinical hypertension thresholds) with a continuous color gradient that conveys relative trends without categorical medical diagnosis.
- **General Wellness Positioning:** Labeling and app messaging were revised to frame blood pressure outputs strictly for general wellness and trend tracking rather than for diagnosing, curing, mitigating, preventing, or treating hypertension or any medical condition.

Key Takeaways

FDA’s new guidance for low-risk general wellness products attempts to provide a variety of examples at the end of its general policy to explain when FDA will or will not consider a wellness-type device to reach the level of a medical device requiring a premarket clearance (510(k), de novo, or PMA).

While these examples may be helpful for many products, there remains a sizable gray area, especially in the wearable devices that provide physiological parameters that are directly tied often to clinical diagnoses. In addition to the new guidance, sponsors of products intended for general wellness should consider reaching out to their trusted attorney or regulatory consultant to confirm whether their device qualifies as a wellness device. In situations of continuing ambiguity, a sponsor should consider requesting an FDA meeting to confirm FDA’s interpretation of the device classification, as well as whether to challenge FDA’s determination when as in WHOOP, FDA revised its initial interpretation.

This blog was drafted by [Brian Malkin](#), co-lead of the Spencer Fane FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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