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FDA Continues to Ease Regulatory Hurdles for Wearable Health Products

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The US Food and Drug Administration (FDA) recently updated two guidance documents applicable to wearable devices and guidance for clinical decision support (CDS) tools, continuing the agency's efforts to ease regulatory hurdles for digital health tools and potentially the use of artificial intelligence.

The updates expand the type of digital health tools, including certain general wellness wearable devices and CDS software that are either exempt from medical device requirements or will be subject to enforcement discretion by FDA.

Key Takeaways

The key takeaways for industry to consider include the following:

- Software functions intended primarily for maintaining or encouraging healthy lifestyles will not likely be regulated as medical devices in and of themselves. However, once such functions begin providing functionality for clinical management or are intended to treat a disease or condition, then the software risks classification as a device.
- CDS tools that analyze patterns or signals are generally regulated as devices while tools that measure physiological parameters that are not specifically intended or marketed for a purpose identified in the device definition are not medical devices.
- FDA has indicated it intends to exercise enforcement discretion for software functions that provide only a single recommendation intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis or treatment of a disease or condition.
- FDA is developing a database to track wearable medical devices, including those with sensor-based digital health technology (sDHT). These sDHT devices are generally subject to premarket notification requirements

Background

FDA regulations require premarket notification or premarket approval for medical devices depending on their risk classification. Medical devices are defined to include an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is … intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man … or intended to affect the structure or any function of the body of man … " and does not include certain software functions excluded by law. Relevant to the updated guidance discussed here, a software function that is intended for maintaining or encouraging a healthy lifestyle is not considered a medical device. Additionally, certain CDS software functions are also excluded from the definition of a device.

Updates to Guidance on General Wellness Products

FDA updated its guidance document entitled "General Wellness: Policy for Low Risk Devices" on January 6, 2026, after originally issuing it on September 27, 2019. The guidance states that FDA "does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices … " General wellness products are products that relate maintenance or encouragement of a general state of health and (1) are intended for only general wellness use, and (2) present a low risk to the safety of users and others. Examples of such products include sleep and activity trackers, products to coach breathing techniques for relaxation, and products that help the user manage a healthy eating plan.

The guidance specifically notes that certain products that use noninvasive sensing to estimate, infer or output physiological parameters (e.g., blood pressure, oxygen saturation) may be general wellness products provided that the products:

- Are noninvasive and not implanted
- Do not involve an intervention or technology that may pose a risk to the safety of users or others if specific regulatory controls are not applied
- Are not intended for the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
- Are not intended to substitute for an FDA-authorized, cleared or approved device
- Do not include claims, functionality, or outputs that prompt or guide specific clinical action or medical management
- Do not include values that mimic those used clinically unless validated (e.g., manufacturer testing, peer-reviewed clinical literature) to reflect those values

FDA explains that such products "may display values, ranges, trends, baselines, or longitudinal summaries, and may contextualize these outputs in relation to sleep, activity, stress, recovery, or similar wellness domains." Such products may also notify a user that evaluation by a healthcare professional may be recommended when outputs fall outside normal ranges.

Updates to Guidance on CDS Software

FDA updated its guidance document entitled "Clinical Decision Support Software" on January 6, 2026, and again on January 29, 2026. By statute, CDS software functions are excluded from the definition of a device if they meet the following criteria under 21 U.S.C. § 360j(o)(1)(E):

1. Not intended to acquire, process or analyze a medical image or signal from an in vitro diagnostic device, or a pattern or signal from a signal-acquisition system
2. Intended for the purpose of displaying, analyzing or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines)
3. Intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis or treatment of a disease or condition
4. Intended for the purpose of enabling a healthcare professional to independently review the basis for recommendations that the software presents so that it is not the intent that such healthcare professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

The updated guidance clarifies FDA's current thinking on the scope of this exemption, primarily as it relates to (1) the type of "pattern or signal" discussed in the first criterion above, the (2) analysis of medical information discussed in the second criterion above, and (3) recommendations for prevention, diagnosis or treatment of a disease or condition as discussed in the third criterion above.

Patterns or Signals

If a CDS product acquires, processes or analyzes patterns or signals, the software will be regulated as a device. In the updated guidance, FDA clarifies that signal acquisition systems measuring signals are those that measure parameters from the body for medical purposes, such as through continuous, near-continuous or streaming measures. FDA also updated the guidance to state that patterns generally do not include discrete, episodic or intermittent point-in-time physiological measurements like routine vital signs taken during a doctor's visit. Consistent with its guidance on general wellness products, FDA noted that activity monitors or other signal acquisition systems that measure physiological parameters that are not specifically intended or marketed for a purpose identified in the device definition are not medical devices.

Medical Information

FDA also clarified its current thinking on CDS products that display, analyze or print "medical information about a patient or other medical information" as described in Point 2 above. FDA continues to interpret medical information about a patient as the type of information used in, or that relates to, the clinical care of the patient, including patient-specific information. Such information is "that which may generally be communicated between healthcare providers (HCPs) in a clinical conversation or between HCPs and patients in the context of a clinical decision." In this guidance, FDA adds that a single, discrete test or measurement result that is clinically meaningful (e.g., a blood glucose lab test result) is medical information, while a more continuous sampling of the same information (e.g., continuous glucose monitor readings) is a pattern/signal. However, recognizing that there is a continuum between a single test and continuous sampling, FDA provided examples that would be considered nondevice functions as long as the products meet all other statutory exemption criteria:

- The report from a radiology study (e.g., "a BIRADS category 4 lesion is present") or summary information about the output of legally marketed CAD software (e.g., "twelve CAD annotations are present")
- An ECG report annotated by an HCP with a description of an abnormal heart rhythm (e.g., "the patient shows signs of atrial fibrillation")
- A blood pressure result (e.g., "120/80 mmHg") from a legally marketed device
- A lab test result (e.g., "potassium level of 4.0 mmol/L or glucose level of 95 mg/dL") in an electronic health record

Recommendation to HCPs

Finally, FDA's updated guidance stated that it intends to exercise enforcement discretion for software functions that provide only a single recommendation intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis or treatment of a disease or condition. This criterion is intended to ensure CDS products are not used to replace or direct an HCP's judgment. However, FDA now intends to exercise enforcement discretion where such functions only provide a single recommendation, as long as the recommendation is clinically appropriate.

General FDA Policy for Wearable Medical Devices

For wearable products that do meet the definition of a medical device, including those that incorporate sDHT, FDA continues to encourage the development of such devices by maintaining a database of devices that have met applicable premarket requirements. FDA intends this list to assist digital health innovators by providing insights into current device landscape and regulatory expectations.

The list includes FDA authorized sDHT devices that are:

- Non- or minimally invasive
- Wearable (such as smartwatches, rings, patches and bands)
- Designed for continuous or spot check monitoring of individuals' health parameters
- Able to be used in nonclinical settings, such as the home

Example products already listed in the database include a variety of smartwatches, tags, blood pressure monitoring systems, sleep aids, glucose monitoring systems and more. The products are listed with links to their 510(k) clearance numbers and/or approval status as applicable.

These sDHT devices are generally subject to premarket notification requirements, meaning the proponent must show that the new device is substantially equivalent to a legally marketed device, comparing the intended use, device features and performance testing. As the database of approved devices continues to grow, the ability for new device manufacturers to make the substantial equivalence showing will become easier.

Please get in touch with your contact at the firm if you have questions about FDA regulation of digital health tools.

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