

# Welcome To Today's CDRH Event

Thanks for joining us!

Today's Topic:

Refresh on General Wellness: Policy for Low Risk Devices

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# Refresh on General Wellness: Policy for Low Risk Devices

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# Final Guidance

- **General Wellness: Policy for Low Risk Devices**
  - [www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices)

# Learning Objectives

- Define general wellness product
- Reiterate FDA's policy for low risk general wellness products
- Clarify how products that perform non-invasive sensing and provide user notifications can be considered general wellness products

# Background

*Contains Nonbinding Recommendations*

**General Wellness:  
Policy for Low Risk Devices  
Guidance for Industry and  
Food and Drug Administration Staff**

Draft Guidance  
published on January  
20, 2015

Final Guidance  
published on July 29,  
2016

Final Guidance  
published on  
September 27, 2019,  
to clarify, per the  
Cures Act, that  
software functions  
intended for  
maintaining or  
encouraging a  
healthy lifestyle are  
not devices

Final Guidance  
published on January  
6, 2026, to clarify  
how non-invasive  
sensing can be  
considered a general  
wellness product



# Policy for Low Risk General Wellness Products

CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the Federal Food, Drug, and Cosmetic (FD&C) Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to:

- Registration and listing and premarket notification requirements (21 CFR Part 807);
- Labeling requirements (21 CFR Part 801 and 21 CFR 809.10);
- Good manufacturing practice requirements as set forth in 21 CFR Part 820 (referred to as the Quality System regulation prior to February 2, 2026 and the Quality Management System Regulation starting February 2, 2026); and
- Medical Device Reporting (MDR) requirements (21 CFR Part 803)

# General Wellness Product

- CDRH defines general wellness products as products that meet the following two factors:
    - are intended for only general wellness use; and
    - present a low risk to the safety of users and other persons.
- 

Section 520(o)(1)(B) of the FD&C Act excludes software functions that are intended for maintaining or encouraging a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition from the definition of device in section 201(h) of the FD&C Act.

# General Wellness Intended Uses

- A general wellness product has
  - 1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or
  - 2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition

*If the product's intended uses are not limited to the above general wellness intended uses, the General Wellness Guidance does not apply.*

# First Category of General Wellness Intended Uses

- An intended use that relates to maintaining or encouraging a general state of health or a healthy activity
- Involves claims about sustaining or offering general improvement to functions associated with a general state of health that **do not make any reference to diseases or conditions**

# First Category of General Wellness

## Intended Uses: Examples



*To promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals*



*To promote relaxation or manage stress*



*To promote physical fitness, such as to help log, track, or trend exercise activity, measure aerobic fitness, improve physical fitness, develop or improve endurance, strength or coordination, or improve energy (such as “fitness” or “activity” trackers)*

# Second Category of General Wellness

## Intended Uses

- An intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition
- Involves claims about sustaining or offering general improvement to functions associated with a general state of health while **making reference to diseases or conditions**

# Second Category of General Wellness

## Intended Uses

- The second category of general wellness claims is comprised of two subcategories:
  - 1) intended uses to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, **may help to reduce the risk of certain chronic diseases or conditions**; and
  - 2) intended uses to promote, track, and/or encourage choice(s) which, as part of a healthy lifestyle, **may help living well with certain chronic diseases or conditions**
- Both subcategories of disease-related general wellness claims should **only** be based on references (such as peer-reviewed scientific publications or official statements made by healthcare organizations) where it is **well understood that healthy lifestyle choices may reduce the risk or impact of a chronic disease or medical condition**

# Second Category of General Wellness

## Intended Uses: Examples



*Product X promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure*



*Software Product Y tracks your caloric intake and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet. Healthy weight and balanced diet may help living well with high blood pressure and type 2 diabetes*



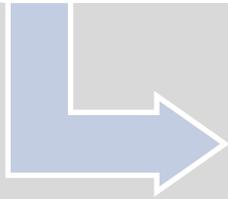
*Product Z tracks activity sleep patterns and promotes healthy sleep habits, which, as part of a healthy lifestyle, may help reduce the risk for developing type 2 diabetes*

# Is the Product Low Risk?



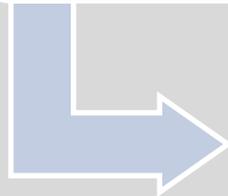
1

- Is the product invasive?



2

- Is the product implanted?



3

- Does the product involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied?

# Examples of Products that would NOT be considered Low Risk



*A laser product that claims to improve confidence in user’s appearance by rejuvenating the skin.*

*Although the claims of rejuvenating the skin and improving confidence in user’s appearance are general wellness claims, laser technology presents risks of skin and eye burns.*



*A neurostimulation product that claims to improve memory would not be considered low risk.*

*Although the claims to improve memory are general wellness claims, the technology itself poses a risk to the user’s safety from electrical stimulation.*



*A continuous glucose meter that uses a microneedle to measure blood glucose.*

*Although claims are related to a general understanding of a user’s health, the product penetrates the stratum corneum and is therefore not a low risk product.*

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# Updates

- Non-Invasive Sensing and General Wellness Products
- User Notifications and General Wellness Products
- New Examples

# Non-Invasive Sensing and General Wellness Products



- FDA may consider certain products that use non-invasive sensing (such as optical sensing) to estimate, infer, or output physiologic parameters (such as blood pressure, oxygen saturation, blood glucose, heart rate variability) to be general wellness products when such outputs are intended solely for wellness uses, and provided they:
  - are non-invasive and not-implanted;
  - do not involve an intervention or technology that may pose a risk to the safety of users or other persons 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; and
  - do not include values that mimic those used clinically unless validated (for example, manufacturer testing, peer-reviewed clinical literature) to reflect those values.

# Non-Invasive Sensing Products that are General Wellness



- Low risk general wellness products that use non-invasive sensing and meet the previously stated criteria may display values, ranges, trends, baselines, or longitudinal summaries, and may contextualize the outputs in relation to sleep, activity, stress, recovery, or similar wellness domains.

# Non-Invasive Sensing Products that are not General Wellness



Products are not general wellness products when:

- They are intended to measure, estimate, or report physiologic values of medical or clinical purposes, including screening, diagnosis, monitoring, alerting, or management of a disease or condition.
- If their labeling, advertising, user interface, or functionality includes any of the following:
  - References to specific diseases, clinical conditions or diagnostic thresholds (excepting products referencing diseases or conditions in a way that meet the second category of a general wellness product).
  - Alerts, alarms, or prompts that recommend or require specific clinical action or medical management.
  - Treatment guidance intended to inform or direct medical management.
  - Claims of clinical equivalence, clinical accuracy, medical or clinical grade, or substitution for an FDA-authorized, cleared, or approved medical device.
  - Intended use statements that explicitly target diagnosis, screening, monitoring or management of a disease or condition.

# User Notifications and General Wellness Products



- For purposes of this guidance, a product may be considered a general wellness product even if it includes a notification informing a user that evaluation by a healthcare professional may be helpful when outputs fall outside ranges appropriate for general wellness use, provided that such notifications:
  - do not identify or name a specific disease or medical condition;
  - do not characterize the output as abnormal, pathological, or diagnostic;
  - do not include clinical thresholds, diagnoses, or treatment recommendations; and
  - do not provide ongoing alerts or monitoring intended to manage a disease or condition.

# New Examples – Example 7

- A wrist-worn wearable product intended to assess activity and recovery that outputs multiple biomarkers, among which are hours slept, sleep quality, pulse rate, and blood pressure. Sleep is measured via an accelerometer, while pulse rate and blood pressure are measured via a photoplethysmogram.
  - Claim relates to general wellness and does not refer to a specific disease or medical condition. Technology for monitoring these biomarkers does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. **Provided the values are validated, this is a low risk general wellness product.**
  - However, if the claims made about any of the product’s functionality implied the product’s use in a medical or clinical context, the product would **not be a low risk general wellness product.**

# New Examples – Example 8

- A wearable product that is intended to provide estimations of blood glucose for monitoring nutritional impacts. The blood glucose measurement is made via minimally invasive microneedle technology, is explicitly contraindicated for use with diabetics and pre-diabetics, and is marketed to users as a means of better understanding their insulin response to certain foods.
  - The claim relates to a general understanding of a user’s health and is specifically contraindicated for use with a specific disease or conditions. This is a general wellness claim. However, the product is invasive, and therefore **not a low risk general wellness product**.

# New Examples – Example 9

- A non-invasive wearable product advertised toward elite athletes and intended for monitoring of several parameters, among which are electrolyte balance, lactate, and hemoglobin. The product is labeled as for use in an exercise/fitness context only, displays values from cleared devices or ranges from the wearable's optical sensor, and is disclaimed for use diagnosing any condition or disorder.
  - Claim relates to general wellness and does not refer to a specific disease or medical condition. Technology for monitoring these physiologic parameters does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. **Provided the values are validated, this is a low risk general wellness product.**

# Summary

- Today we discussed the FDA guidance, “General Wellness: Policy for Low Risk Devices,” including clarifications to the guidance issued on January 6, 2026.
- These clarifications were focused on products that use non-invasive sensing and provide user notifications.
- Examples were discussed to illustrate the policy clarifications.



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# Questions and Answers

# Closing Remarks

# Thanks for Joining Today!



- **Materials will be available at CDRH Learn**
  - [www.fda.gov/Training/CDRHLearn](http://www.fda.gov/Training/CDRHLearn)
- **Additional questions about today's event**
  - Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
- **Upcoming CDRH Events**
  - [www.fda.gov/CDRHEvents](http://www.fda.gov/CDRHEvents)



Start Here/The Basics! (Updated 10/29/2024) <a href="#">MDUFA Small Business Program, Registration and Listing</a>	▼
How to Study and Market Your Device - (Updated module 12/19/25) 510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification	▼
Postmarket Activities (Updated 12/30/25) Quality System, QMSR, Exporting, Device Recalls, MDR, Inspection - Global Harmonization	▼
In Vitro Diagnostics - (Updated 12/06/24) IVD Development, CLIA, and Virtual Town Hall Series	▼
Unique Device Identification (UDI) System	▼
<b>Specialty Technical Topics - (Updated 7/29/25)</b>	▼
Radiation-Emitting Products	▼
510(k) Third Party Review Program (for Third Party Review Organizations)	▼
Industry Basics Workshop Series	▼



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