

# General Wellness & Low-Risk Digital Health Products

## A QUICK REFERENCE DOCUMENT

### General Wellness Products

According to the [FDA](#), **General Wellness Products** comply with the following two factors:

1. Are intended for *only* general wellness use, defined as an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, and
2. Present a low risk to the safety of users and other persons.

There are 2 types of claim categories for General Wellness Products:

#### Claim Category 1

Product's intended use relates to maintaining or encouraging a general state of health or a healthy activity	These products <b>do not make any reference</b> to diseases or conditions.
	<i>Examples:</i> <ul style="list-style-type: none"><li>• weight management,</li><li>• physical fitness, including products intended for recreational use,</li><li>• relaxation or stress management,</li><li>• mental acuity,</li><li>• self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem), and</li><li>• sleep management or sexual function.</li></ul>

## Claim Category 2

Product's intended use relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition

These products make reference to diseases or conditions in describing:

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.

*Examples:*

- A digital health software product coaches breathing techniques and relaxation skills, which, as part of a healthy lifestyle, may help living well with migraine headaches.
- A digital health software product tracks and records your sleep, work and exercise routine which, as part of a healthy lifestyle, may help living well with anxiety.
- A digital health product promotes making healthy lifestyle choices such as getting enough sleep, eating a balanced diet, and maintaining a healthy weight, which may help living well with type 2 diabetes.
- A digital health product that promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.
- A digital health software product that tracks your caloric intake and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet, which may help living well with high blood pressure and type 2 diabetes.
- A digital health product that 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.



## Low Risk Products

The general wellness criteria applies only to general wellness products that are low risk. If your answer to any of the following questions is **YES**, the product is not 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, such as risks from lasers or radiation exposure?
4. Is the product actively regulated by the FDA?

The following are examples of products that would not be considered “low risk”:

- A neurostimulation product that claims to improve memory, but electrical stimulation presents a risk to the user.
- A product that claims to enhance a user’s athletic performance by providing suggestions based on the results of relative lactic acid testing, when the product uses venipuncture to obtain the blood samples needed for testing. Such a product is not low risk because it is invasive (e.g., obtains blood samples by piercing the skin), and also because the product involves an intervention that may pose a risk to the safety of the user and other persons if specific regulatory controls are not applied (e.g., venipuncture may pose a risk of infection transmission).
- Implants promoted for improved self-image or enhanced sexual function. Implants pose risks to users, including possible rupture or adverse reaction to implant materials, as well as risks associated with the implantation procedure.
- Sunlamp products promoted for tanning purposes, which risk a user’s safety due to the ultraviolet radiation, including, without limitation, an increased risk of skin cancer.
- A laser product that claims to improve confidence in users’ appearance by rejuvenating the skin. Although the claims of rejuvenating the skin and improving confidence in the user's appearance are general wellness claims, laser technology presents risks of skin and eye burns.





## 6 Illustrative Examples of General Wellness Products

### 1 A software function plays music to “soothe and relax” an individual and to “manage stress.”

This software function has claims that relate only to relaxation or stress management, not to any disease or medical condition, and thus are general wellness claims. In addition, the technology to play music does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors to qualify as a low risk general wellness product.



### 2 A software function that solely monitors and records daily energy expenditure and cardiovascular workout activities to “allow awareness of one’s exercise activities to improve or maintain good cardiovascular health.”

This software function has a claim that relates to a specific organ only in the context of general health and does not refer to a disease or medical condition. In addition, although the monitoring or recording of exercise activities present risks (such as inaccuracy), when made in the absence of disease or medical condition claims, the technology does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors to qualify as a low risk general wellness product.



### 3 A software function monitors and records food consumption to “manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity.”

This software function has a claim that relates to dietary choices and weight management, and thus is a general wellness claim. In addition, the technology for monitoring or recording food consumption does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors to qualify as a low risk general wellness product.



**4 A software function that reminds users to keep exposed skin out of direct sunlight when the UV index is high, which, as part of a healthy lifestyle, may help reduce the risk of skin cancer.**

This claim relates to tracking preventive measures which, as part of a healthy lifestyle, may help reduce the risk of a medical condition. The claim is for a healthy lifestyle choice and it is generally accepted that the choice may play an important role in health outcomes. Thus, it is a general wellness claim. In addition, the technology reminding users to keep exposed skin out of direct sunlight does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors to qualify as a low risk general wellness product.



**5 A portable product that is intended to monitor the pulse rate of users during exercise and hiking.**

This claim relates only to exercise and hiking and does not refer to a disease or medical condition. Thus, it is a general wellness claim. In addition, the technology for monitoring pulse rate does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors to qualify as a low risk general wellness product.



**6 A product is intended to mechanically exfoliate the face, hands and feet to make the skin smoother and softer. The product cannot be used in a manner that penetrates or pierces the skin.**

This claim relates to self-esteem and does not refer to a specific disease or medical condition, and thus is a general wellness claim. In addition, the product is noninvasive as it does not penetrate the stratum corneum and the technology for exfoliating the face does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors to qualify as a low risk general wellness product.



*Note: If the product is intended to exfoliate the skin in order to enhance the delivery of a topically applied product containing one or more active pharmaceutical ingredients through the stratum corneum, the product would be considered to be invasive. Therefore, the product would not be a low risk general wellness product.*

Source: [General Wellness: Policy for Low Risk Devices](#)

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