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US FDA drafted guidelines for wellness medical devices

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The United States Food and Drug Administration (US FDA) has issued two draft guidance documents outlining how the agency would classify low-risk general wellness devices and applications. It has also proposed risk assessment-based regulation for medical device accessories.

According to the proposed guidance, the FDA intends to regulate a general wellness product when it is marketed for a specific disease or condition. Devices that are more intrusive and involve more than tracking of exercise, diets and heart rates would require more regulatory oversight.

Devices are not considered general wellness if they purport to treat or diagnose obesity, anorexia, anxiety, muscle atrophy or erectile dysfunction. Also, computer games that claim to diagnose or treat autism do not fall under the definition of a general wellness product.

The regulatory body in a draft guidance defined a medical device accessory as something that is used with at least one parent device or is intended to support, supplement and/or augment the performance of one or more parent devices.

The accessories will be regulated based on the risks they present when used with their parent devices, but not based on the parent device's risks. The agency noted that some device accessories can have lower associated risks than their parent devices, and thus warrant different levels of regulation.