

# Wearable Systems and Equipment Policy, Definitions, Use Cases

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Study Session 8  
Wearable Systems and Equipments

## Outline

- General Wellness Devices (guidance of the FDA)
- Use Cases
- Market forecast
- Technical considerations
- Topics to be addressed in stage 0 project



## Policy and Definition

- **General Wellness: Policy for Low Risk Devices**
- Draft Guidance for Industry and Food and Drug Administration Staff
- Document issued on: January 20, 2015
- Compliance policy (draft) for low risk products that promote a healthy lifestyle
- <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf>
- **Definition: A general wellness product has**
  - (1) an intended use that relates to a maintaining or encouraging a general state of health or a healthy activity, or
  - (2) an intended use claim that associates 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).

## Low Risk

- Whether a device is low risk for purposes of this guidance is determined by whether or not the product:
  - is invasive (penetrates the skin)
  - involves an intervention or technology that may pose a risk to a user's safety
  - if device controls are not applied, such as risks from lasers, radiation exposure, or implants;
  - raises questions of biocompatibility
- If the answer to any of these questions is **yes**, the device is **not** a low risk device and not covered by this guidance

## Claims of general wellness products

- weight management
- physical fitness, including products intended for recreational use
- relaxation or stress management
- mental acuity
- self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem)
- sleep management
- general mobility or to assist individuals who are mobility impaired or who have limited mobility in a recreational activity

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## Use Cases (1)

<b>Use Case 1</b>	<b>A mobile application plays music to “soothe and relax” an individual and to “manage stress.”</b>
General wellness claims	These claims relate only to relaxation or stress management, not to any disease or medical condition, and thus are general wellness claims.
Low risk	The technology to play music does not present inherent risks to a user’s safety.
<b>Use Case 2</b>	<b>A portable product that claims to monitor the pulse rate of users during exercise and hiking.</b>
General wellness claims	This claim relates only to exercise and hiking and does not refer to a disease or medical condition.
Low risk	The technology for monitoring poses a low risk to the user’s safety.

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## Use Cases (2)

Use Case 3	A mobile application 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.”
General wellness claims	This claim relates to a specific organ only in the context of general health and does not refer to a disease or medical condition.
Low risk	To the extent the monitoring or recording exercise activities present risks (such as inaccuracy), when made in the absence of disease or medical condition claims, the risks to the user’s safety are low.

## Use Cases (3)

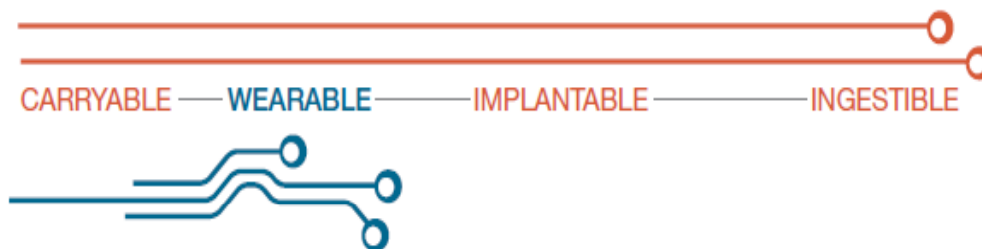
Use Case 4	A mobile application monitors and records food consumption to “manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity”.
General wellness claims	This claim relates to dietary choices and weight management, and thus is a general wellness claim.
Low risk	The technology for monitoring or recording food consumption poses a low risk to the user’s safety

## Use Cases (4)

Use Case 5	A product is intended to mechanically exfoliate the face, hands and feet to make the skin smoother and softer.
General wellness claims	This claim relates to self-esteem and does not refer to a specific disease or medical condition.
Low risk	The technology for exfoliating the face poses a low risk to the user's safety as it does not penetrate the stratum corneum.

## Progression Chart for wearables in the future

WEARABLE



Source: The Next Familiar, A collaborative project by Karen Maxwell and Shannah Segal, OCAD University 2014

## Wearables Definition

- Devices with a form factor meant to be attached to the body, that can perform computational tasks either inherently or by connection to a companion system or network.
- Examples:
- These include fitness or activity trackers e.g. Fitbit (launched 2008), Jawbone Up (launched 2011) and Nike Fuelband (launched 2012).
- Smartwatches may or may not have built-in sensors that allow them to perform the same functions as activity trackers. Many (but not all) smartwatches sync to another device, commonly a smartphone.

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## Definition Implantables

- Difference to wearables: **crossing the skin barrier as dividing line between wearable and implantable**
- Example a 'Biostamp' — a paper-thin electronic membrane that can be affixed to the body like a plaster, that is 'closer' than a wearable but not quite implanted.
- Device that necessitates piercing or cutting into the bodies is an implantable, whereas a 'smart' contact lens worn on the eye or an e-tattoo applied to the skin is a wearable.
- Implantables are not easily removed and have a greater level of permanence and incorporation into the body.

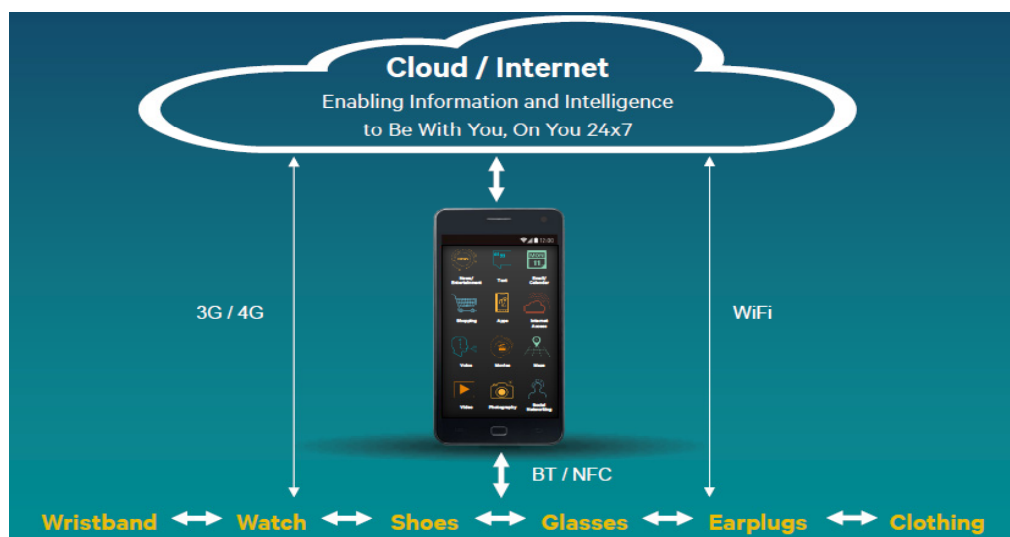
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## Definition Ingestibles

### Examples

- Pill cameras that capture images and transmit them as they travel through the body
- Pill sensors that measure biometric data and transmit that data for analysis

## Smartphone as personal companion (hub)



## Connected Personal Health Products (US market forecast)

### CONNECTED PERSONAL HEALTH PRODUCTS: U.S. MARKET UNIT SALES (#M)

	2013	2014	2015	2016	2017	2018	2013-2018 CAGR
<b>ECG for Personal Use</b>	0.004	0.008	0.011	0.015	0.029	0.067	<b>73%</b>
<b>Insulin Pump</b>	0.071	0.076	0.086	0.097	0.117	0.134	<b>13%</b>
<b>Personal Emergency Response System</b>	0.092	0.135	0.249	0.374	0.451	0.567	<b>44%</b>
<b>Pulse Oximeter</b>	0.040	0.119	0.219	0.266	0.557	1.004	<b>90%</b>
<b>Pill box/dispenser</b>	0.091	0.151	0.220	0.294	0.531	1.077	<b>64%</b>
<b>Glucometer</b>	0.190	0.315	0.488	0.714	0.955	1.256	<b>46%</b>
<b>Blood Pressure Monitor</b>	0.411	0.631	0.862	1.178	1.512	1.942	<b>36%</b>
<b>Total</b>	<b>0.900</b>	<b>1.434</b>	<b>2.134</b>	<b>2.938</b>	<b>4.153</b>	<b>6.047</b>	<b>46%</b>

(source: Technology Trends to Watch 2015, CEA)

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## Connected Wellness Products (US market forecast)

### CONNECTED WELLNESS PRODUCTS: U.S. MARKET UNIT SALES (#M)

	2013	2014	2015	2016	2017	2018	2013-2018 CAGR
<b>Digital Pedometer/ Activity Tracker</b>	4.0	5.6	7.9	11.2	14.5	16.6	<b>33%</b>
<b>Heart Rate Monitor</b>	0.5	0.6	0.9	1.3	1.8	2.1	<b>36%</b>
<b>GPS Sport Watch</b>	0.5	0.6	0.9	1.4	2.2	2.7	<b>41%</b>
<b>Digital Weight Scale</b>	2.7	4.0	5.8	7.0	8.1	9.2	<b>28%</b>
<b>Sleep Quality/Diet Monitoring/ Stress Management Products</b>	0.1	0.3	0.5	1.0	1.8	2.4	<b>75%</b>
<b>Total</b>	<b>7.8</b>	<b>11.1</b>	<b>16.0</b>	<b>21.9</b>	<b>28.4</b>	<b>33.0</b>	<b>34%</b>

(source: Technology Trends to Watch 2015, CEA)

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## Technical considerations for wearable devices

- microprocessors and their related circuits
- connectivity with other devices such as smartphones, Wi-Fi networks, etc.
- batteries to supply power to the devices
- battery chargers to recharge the batteries
- power generation
- sensors for monitoring various activities or bodily functions (breathing, heart rate, and blood sugar)
- displays for providing feedback directly to the user
- chemicals or materials including the fabrics the components are mounted on and the materials that make up the components

(Source: The Wearables Revolution, IEEE 2014)

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## Technical requirements and standards related to wearable devices

- Product safety—includes risks with the battery and battery charger.
- EMC—the potential to interfere with or be affected by other products
- Wireless regulatory—does the product use the radio spectrum in an appropriate manner
- Interoperability—does the system interact with other devices as intended
- Energy efficiency—particularly for the charger
- Product performance—are there product performance claims that need to be validated?
- Chemical—are there regulated chemicals that make up part of the product
- Sustainability—are there environmental concerns with basic materials of the product or even the product over its entire lifecycle
- Security and privacy—are there security or privacy concerns with the product, particularly relevant for financial or health-related information

(Source: The Wearables Revolution, IEEE 2014)

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## Topics to be addressed in stage 0 project

- Define wearables within the scope of TC 100
- Define wearables related definitions and taxonomy
- Define wearables related use cases and user requirements
- Identify technical requirements based on use cases
- Identify standards and regulations for wearables
- Analyse standards gaps and propose NPs

## • QUESTIONS ?