

# Checklist

## for 513(g) Request

The FDA 513(g) request is a request for information regarding classification and regulatory requirements applicable to the digital health product that will potentially aid in informing the appropriate regulatory pathway for the product. The request is used to determine whether a product is subject to regulation. If you are planning to submit a 513(g) request, here is a checklist of things you may need to consider:

### 4 KEY ELEMENTS

The 513(g) Request for Information should contain 4 key elements:

#### 1. Cover letter

- Date of request
- Product name
- Question(s): Specific inquiry about product class, applicable regulatory requirements, etc.
- Requestor's information:
  - Full name
  - Address
  - Contact number
  - Fax number (*if applicable*)
  - Email address
- 513(g) requestor's signature

#### 2. Product description (*as applicable*)

- List of materials and components used in/with the product
- Photographs, engineering drawings, and/or samples of the product
- Summary of the product's operational principles
- Description of the type and amount of energy to be used or delivered by the product
- Description of similar products in commercial distribution in the United States (*if available*)

#### 3. Product use description (*e.g., what the device is to be used for*)

- Disease or condition for which the product is to be used
- Product delivery type: prescription vs. over the counter
- Part of the body or type of tissue applied to or interacted with
- Frequency of use
- Physiological purpose
- Patient population
- Any other labeling information related to patient use of the product

4. As applicable/available, any **proposed labeling or promotional material for the device** and any labeling or promotional material of a similar, legally marketed device, if available.
- If **available/applicable**, any proposed labeling, including proposed promotional material for the device or any labeling or promotional material of a similar, legally marketed device
  - If **not available/applicable** but proposed labeling is available for the described device or for a similar legally marketed device, note this fact in the cover letter

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