Before you go through the tool,

**STARTING POINT**

Has a product with low risk as defined by the

- Has an intended use that relates between healthy

- The product provides or facilitates supplemental clinical care

- Exempt

Individuals/patients or caregivers

1. Do any of the following three statements apply to your digital health product?

2. Does your product have the same intended use?

3. Are different technological characteristics of your product(s) or analyzing medical product data.

4. Is your product connected to a predicate device?