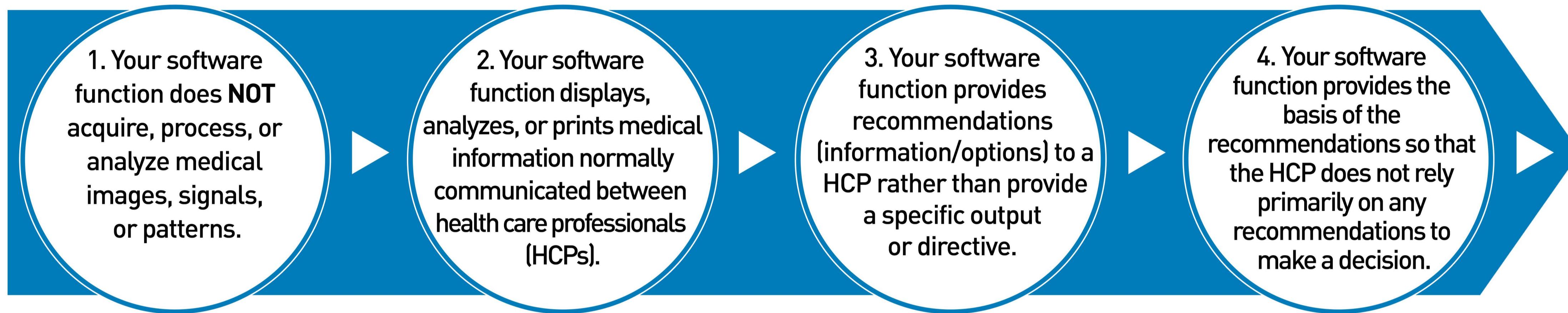


# Your Clinical Decision Support Software: Is It a Device?

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions. \*

## Your software function must meet all four criteria to be Non-Device CDS.

### Summary interpretation of CDS criteria



**Your software function may be non-device CDS.**

### Non-Device Examples

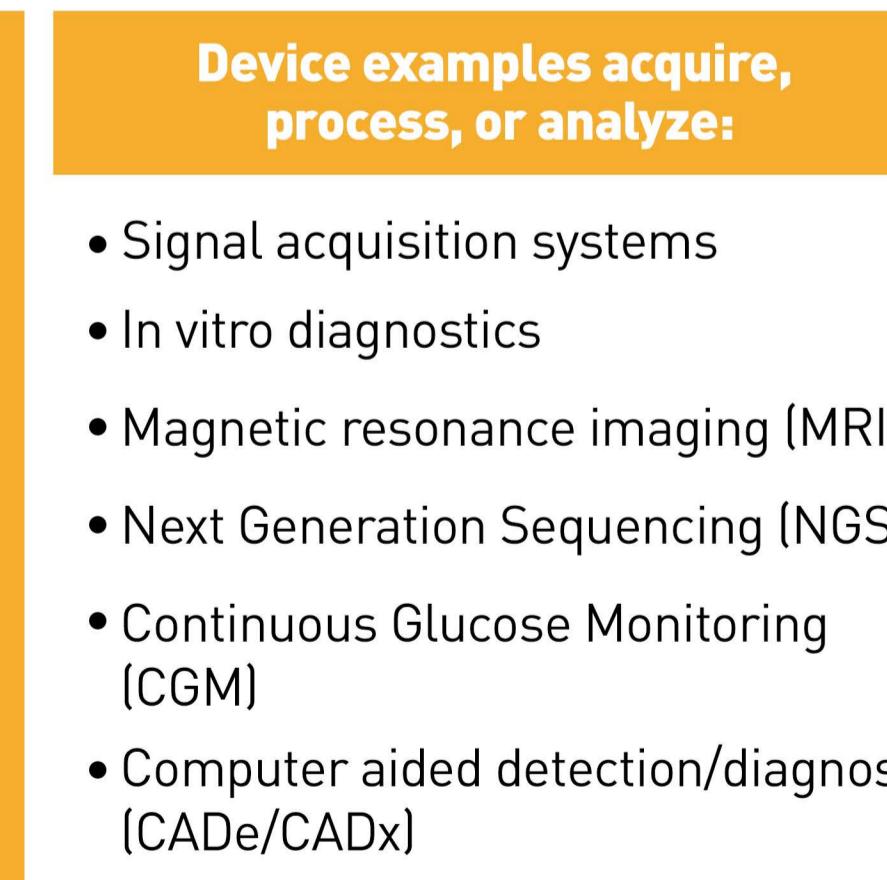
#### Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:

**AND**

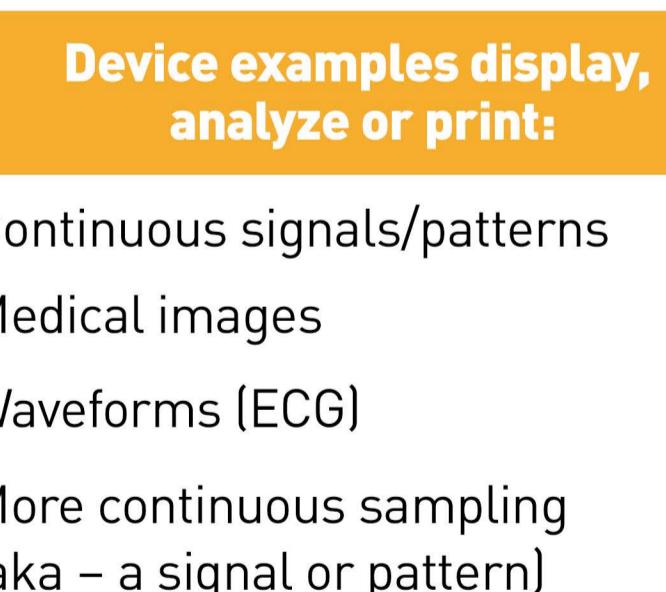
#### Non-Device examples provide:

**AND**

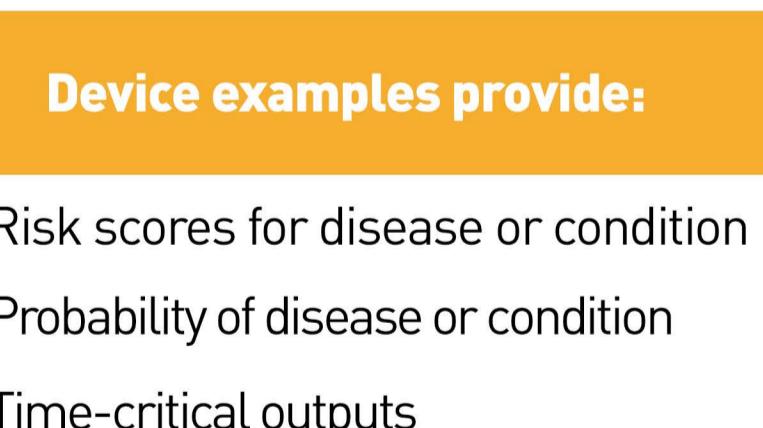
#### Non-Device examples provide:



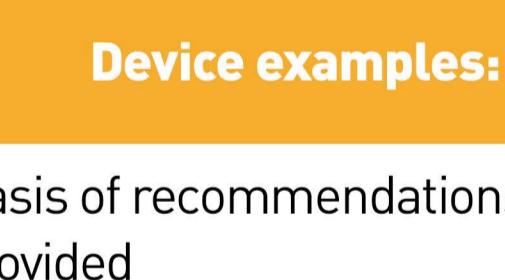
**OR**



**OR**



**OR**



**Your software function is a device.**

**\*Disclaimer:** This graphic gives a general overview of Section IV of the guidance ("Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act"). Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.