

# CLINICAL DECISION SUPPORT TOOLS: WHEN DO FDA REGULATIONS APPLY?

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Version 1: 09/27/2022

**START: The proposed solution in this study  
(either now or in the future) ...**

**is intended to acquire, process or analyze medical  
images, signals, or patterns**  
(x-ray, ultrasound, MRI, ECGs, CTs, Next Generation  
Sequencing, Continuous Glucose Monitors, Computer Aided  
Diagnostics, etc.).

YES

No

**...will only display, analyze, or print medical information that  
is normally communicated between HCPs**  
(e.g., symptoms, certain test results, discharge summaries, clinical  
practice guidelines, etc.).

NO

(e.g., involves continuous signals,  
patterns, medical images,  
waveforms, etc.)

YES or N/A

**...is intended to support HCP (not make decisions on behalf of) AND  
provides information and/or lists of options to the HCP or Caregiver**  
(such as a list of preventive diagnostics, or possible treatment options)

No

(e.g., provides single or specific outputs,  
risk scores, probability of disease  
or condition, or time-critical outputs  
such as sepsis, stroke, or heart failure)

YES or N/A

**provides, in plain language, the basis of its recommendations, e.g.,:**  
**(a)** relevant patient-specific information and other knowns/unknowns  
(missing or unexpected input values);  
**(b)** a description of the underlying algorithm development and validation;  
**(c)** data the model validation/testing relied upon, and  
**(d)** a description of the results from clinical studies conducted to validate the  
algorithm

No

YES

**FDA Considerations Do Not Apply**

**FDA  
Considerations  
Apply**

Based on FDA Sept 2022 Updated Guidance