ARKA
ARKA-PROTO - Non-Device Clinical Decision Support position
v1.0.0 25 August 2026
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This section states ARKA's reasoning for why ARKA-PROTO is designed to meet the four Non-Device Clinical Decision Support criteria under FD&C Act ?520(o)(1)(E), as interpreted in FDA's January 2026 final guidance on Clinical Decision Support Software (Docket FDA-2017-D-6569). It is ARKA's own analysis of this module only. It is not a legal opinion, not a regulatory conclusion, and does not apply to any other ARKA product unless that product publishes its own position.

STATUTE AND GUIDANCE

FD&C Act ?520(o)(1)(E) excludes software functions from the device definition when four criteria are met. FDA's January 2026 final guidance supersedes the September 2022 version. The four criteria are unchanged in substance; the January 2026 revision sharpens explainability and automation-bias expectations under criterion 4.

FOUR CRITERIA - HOW ARKA-PROTO MEETS EACH

Criterion 1. Not acquire, process, or analyze medical images or signals
The software function does not acquire, process, or analyze medical images or signals from in vitro diagnostic devices.
ARKA-PROTO assembles structured chart facts, report text, and device records. It does not read DICOM pixels, waveforms, or acquisition frames. A reachability test fails the build if a Criterion-1 surface becomes callable from lib/proto/.
Check: CHECK-PROTO-8

Criterion 2. Display, analyze, or print medical information
The software function is intended for displaying, analyzing, or printing medical information about a patient or other medical information.
Every protocol proposal cites closed evidence ids from the catalog, RSNA Radiology Playbook codes, and gate reason codes drawn from published contrast, pregnancy, and implant guidance - not free-text model output on the determining path.
Check: CHECK-PROTO-1

Criterion 3. Support or provide recommendations to a licensed HCP
The software function is intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition.
Protocol selection resolves to Auto, Assisted, Escalate, or Return-to-sender. Auto requires a named physician attestation for the indication class; every auto-protocoled study can be reversed before acquisition. The engine supports the radiologist; it does not place orders or block acquisition.
Check: CHECK-AUT-1

Criterion 4. Enable independent review of the basis
The software function is intended for the purpose of enabling such health care professional to independently review the basis for such recommendations.
The radiologist worklist shows autonomy tier and rule, four ontology layers, all seven safety-gate results, patient-state inputs, and candidates that were not selected - with no determining fact behind a click.
Check: lib/proto/worklist/copy.ts (Criterion 4 surface)

FOUR ARCHITECTURAL RULES

Rule 1. Never reads an image
The protocol engine never reads an image. Its inputs are the chart, the report text and the device record - and a reachability test fails the build if a pixel path becomes callable from the protocol module.
Check: CHECK-PROTO-8

Rule 2. Cannot see the payment rate
No reimbursement amount, payer identity, site-of-service payment differential or contract rate is an input to protocol candidate generation, gate evaluation, or the autonomy tier - and a test fails the build if one becomes reachable from that code path.
Check: CHECK-PROTO-2

Rule 3. No auto without a named physician
No study is protocoled without a human in the loop unless a named licensed physician at that site has signed the specific indication class, at a recorded version and date, and any auto-protocoled study can be reversed by a radiologist at any point before acquisition.
Check: CHECK-AUT-1 attestation gate on auto tier

Rule 4. Candidate sources cannot clear gates or set autonomy
A candidate source implements exactly one method - propose - and cannot clear a gate, set an autonomy tier, write to a RIS, or read data not on ProtocolContext. Generative and retrieval sources are registered but disabled by default.
Check: CHECK-PROTO-4 CHECK-PROTO-5

WHAT WOULD CHANGE THE ANALYSIS

A fully autonomous tier that protocoled studies without a named physician attestation for the indication class would move the analysis toward device regulation - the attestation requirement is load-bearing.