Start

Is the SW a computer program?

Yes

Is the SW embedded in the device?

Yes, then regulated as part of device

No

Does the SW perform an action that's different from storage, archival, simple search?

Yes

Is the SW to benefit the individual patient(s)?

Yes

Action in scope of intended use regulated by the FDA?

Yes

Accessory to a Medical Device?

No

Out of scope of FDA

In scope of FDA

No