











4.A: Is the software function intended to serve as electronic patient records, or to transfer, store, convert formats, or display electronic patient records that are the equivalent of a paper medical chart?

Yes

No

Continue to Question 4.B.

See "Changes to Existing Medical Software Policies" [Guidance](#)

Your product may be a device. Go to Step [5](#).

4.B: Is the software function intended for interpretation or analysis of patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition?

Yes

No

Your product may be a device. Because you answered "Yes" to Question 4.B, the next relevant question is in Step [6](#).

Continue to Question [4.C](#).

















