Question for the Committee

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Proposal

Reclassify HIV serology and NAT point of care and lab-based diagnostic and supplemental tests from Class III to Class II

Not included are HIV assays for:

- Blood donor screening
- Home use
- Viral load monitoring
- Phenotypic drug resistance

Question before the Committee

Do committee members believe that special controls as described, in addition to general controls, are sufficient to mitigate the risks to health presented by reclassification of HIV serology and NAT point of care and laboratory-based diagnostic and supplemental devices?

In addressing this question, please discuss additional risks and/or special controls that we should consider.

Thank you!

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https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm