FDA Regulation of HIV Self-Testing Devices and Self-Collection Kits for HIV Diagnosis

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In Vitro Diagnostic devices are medical devices per 201(h) of Food, Drug, & Cosmetic (FD&C) Act [21 CFR 809.3]

Medical devices are

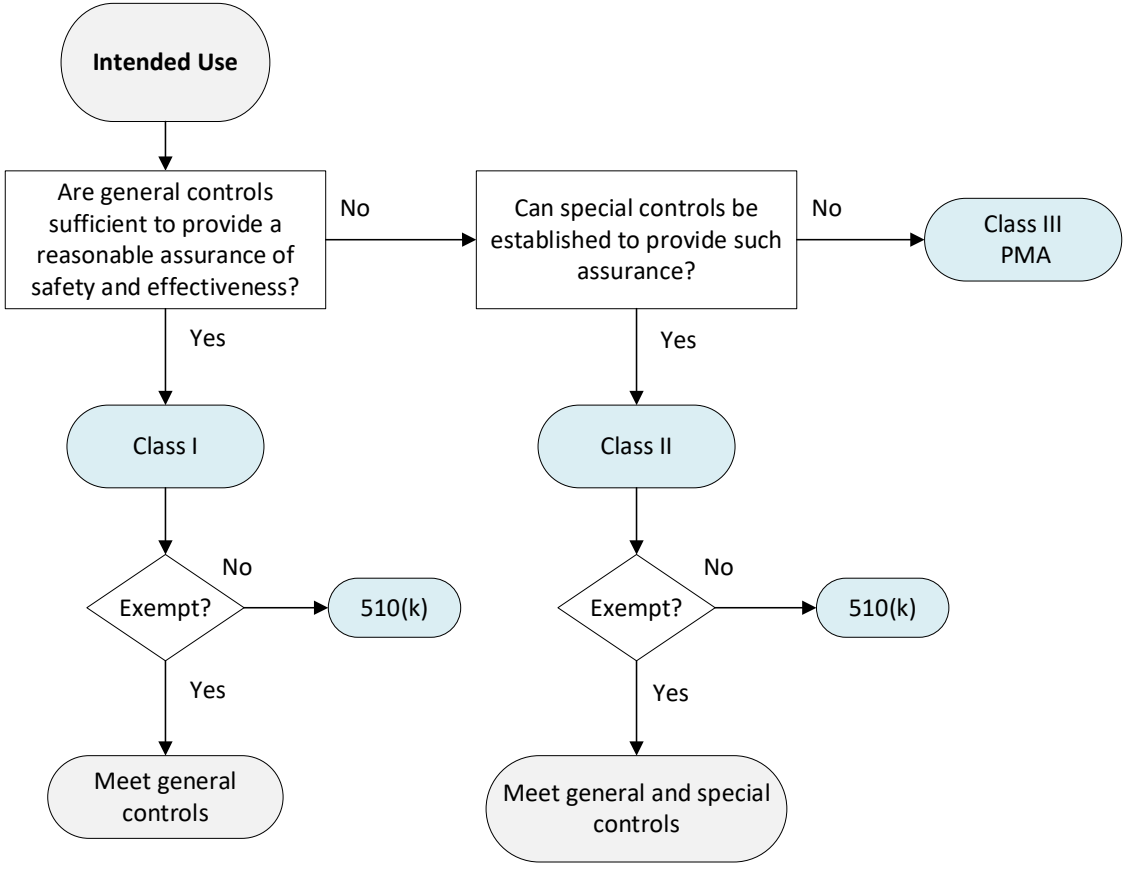
- Reagents, instruments, and systems used in diagnosis of disease or other conditions…in order to cure, mitigate, treat, or prevent disease
- Intended for use in the collection, preparation, and examination of specimens taken from the human body

Section 513(a)(1) of the Food, Drug, and Cosmetics Act, 21 U.S.C § 360c(a)(1)

Review of IVDs is based on:

The balance of benefit/risk to the individual

A reasonable assurance of safety and effectiveness of the device



FDA regulation of HIV Self-Testing devices

HIV Self-Testing (HIVST) devices are class III medical devices

HIVSTs require approval of a PMA before they can be marketed

- There is one approved self-testing device (OraQuick HIV in-home test, approved in 2012)
- HIVST were not included in the reclassification of HIV diagnostic, supplemental, or viral load tests due to a lack of sufficient experience with these devices to write special controls

However

- FDA agrees that there is an urgent need to improve access to HIVST
- FDA is working with manufacturers and will consider alternative validation strategies, e.g., based on the regulatory status of the device (approved PoC claim vs. no approved claim) to expedite entry to market

FDA regulation of HIV self-collection kits

HIV self-collection kits require FDA approval

Self-collection kits are medical devices

- Review pathway is determined by the Intended Use (e.g., home use or clinic; supervised or unsupervised, etc.)

Adequate and appropriate sample collection is essential for a device to meet performance expectations

- Self-collection→ untrained individual collects their own sample
- No automatic assurance that collection has been performed appropriately
- FDA reviews instructions for sample collection and the device's performance with the intended sample type to ensure a reasonable assurance of safety and effectiveness of the device

501(f)(1)(B) of the FD&C Act, 21 U.S.C. § 351(f)(1)(B); 502(o) of the Act, 21 U.S.C. § 352(o); and 301(k) of the Act, 21 U.S.C. § 331(k)

Current landscape

FDA recognizes there is a need for self-collection kits for HIV diagnosis for individuals unable or unwilling to attend a clinic

But

- HIV self-collection kits require approval of a PMA* to comply with the FD&C Act
- Distribution of unapproved HIV self-collection kits is a violation of the Act#
- There are no FDA-approved HIV self-collection kits that use blood samples currently on the market

* Or clearance of a 510(k) following reclassification of HIV diagnostic devices

See 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B); 502(o) of the Act, 21 U.S.C. § 352(o); and 301(k) of the Act, 21 U.S.C. § 331(k)

FDA's goal is to bring unapproved/uncleared devices into compliance with the law and regulations

In the interest of public health, FDA is committed to working with device developers to meet the requirements

Come talk to us!

Guidance on the Qsub process: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program Guidance for Industry and Food and Drug Administration Staff (2021)*

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Questions?

Disclaimer: My responses are an informal communication and represent my own best judgment. These comments do not bind or obligate FDA

Thank you!

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