FDA review of Drugs of Abuse (DoA) assays

Drug Testing Advisory Board (DTAB) Meeting
December 5th, 2023

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Drugs of Abuse (DoA) Review

- Generally, drugs of abuse assays are reviewed and 510(k) cleared for detection of drugs of abuse around specific cutoffs
- Reviewed under least burdensome principles
  - "We define "least burdensome" to be **the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time.**"

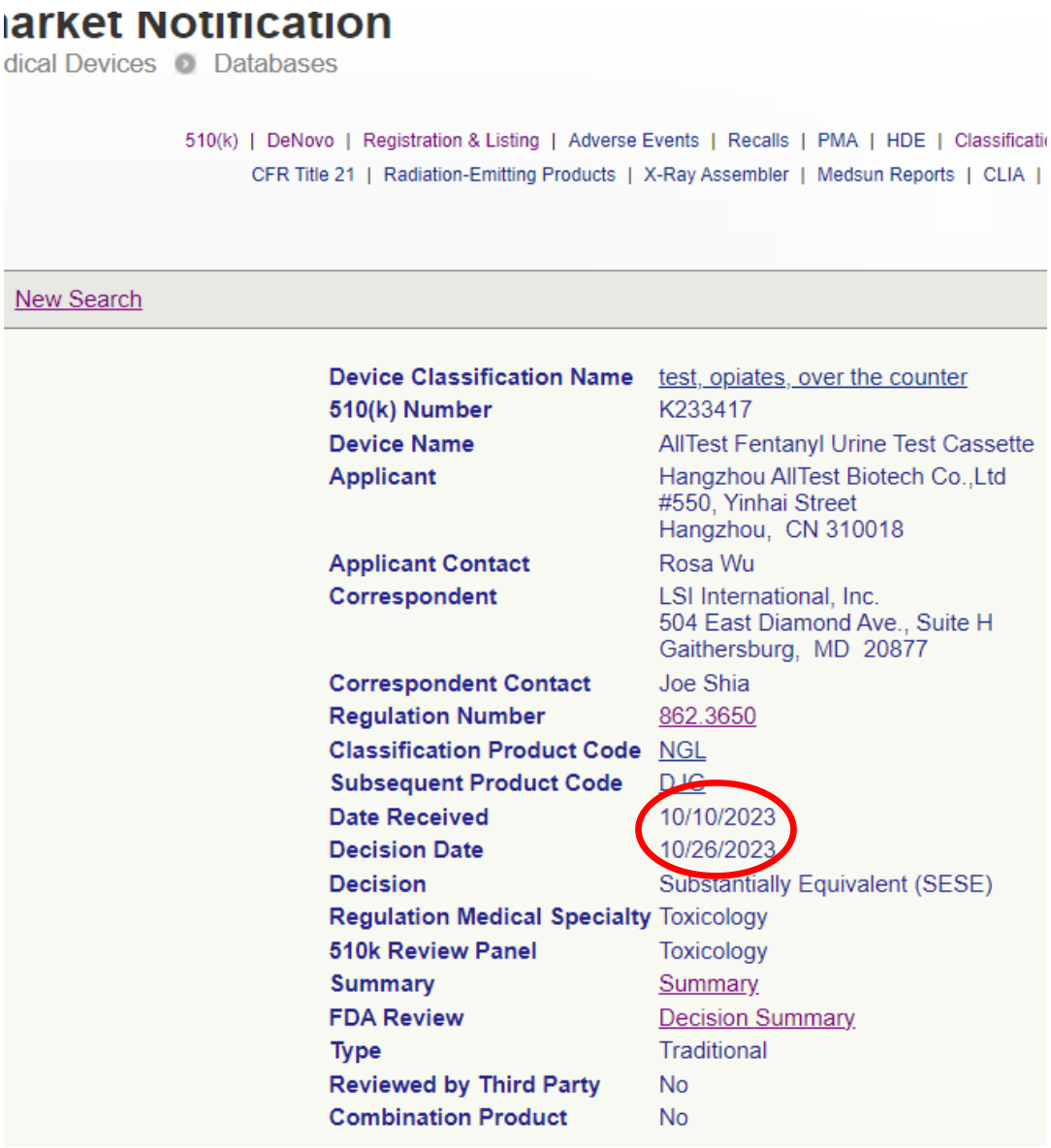
- *How to determine the minimum amount of information necessary?*

https://www.fda.gov/medical-devices/in-vitro-diagnostics/drugs-abuse-tests

510(k) database

- How to design study protocols to support a substantially equivalent decision?
- Device manufacturers can use:
  - Summary of predicate testing described in decision summaries in the FDA 510(k) database
  - Previous FDA presentations
    - FDA Regulation of Drugs of Abuse Tests, July 26, 2016 (Courtney Lias, Ph.D.)
    - FDA Regulation of Drugs of Abuse Tests, March 9th, 2022 (Joey Kotarek, Ph.D.)
  - SAMHSA guidelines can also help
    - final-mg-oral-fluid.pdf (samhsa.gov)

Triage Review Program



arket Notification

dical Devices ◉ Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classificati

CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA |

New Search

Device Classification Name	test, opiates, over the counter
510(k) Number	K233417
Device Name	AllTest Fentanyl Urine Test Cassette
Applicant	Hangzhou AllTest Biotech Co.,Ltd #550, Yinhai Street Hangzhou, CN 310018
Applicant Contact	Rosa Wu
Correspondent	LSI International, Inc. 504 East Diamond Ave., Suite H Gaithersburg, MD 20877
Correspondent Contact	Joe Shia
Regulation Number	862.3650
Classification Product Code	NGL
Subsequent Product Code	DJG
Date Received	10/10/2023
Decision Date	10/26/2023
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Toxicology
510k Review Panel	Toxicology
Summary	Summary
FDA Review	Decision Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

FDA looks for complete, well organized 510(k) submissions with high quality data to review under the triage program

Pre-determined Change Control Plan (PCCPs)

- Section 515C of the FD&C Act provides FDA with express authority to approve or clear PCCPs for devices requiring premarket approval or premarket notification.
  - For example, this section provides that new premarket notifications are not required for a change to a device that would otherwise require a new 510(k) if the change is implemented according to a PCCP previously cleared by FDA.

- Example from other Device Types:
  - Breakpoint change protocols reviewed in k222430

Additional Resources: Q-Submission Program

- Mechanism to ask FDA for feedback about a planned premarket submission, for example:
  - Is the proposed predicate device appropriate if we demonstrate substantial equivalence?
  - Is the proposed lay user study adequate to support over-the-counter use of the device?
- Teleconference as well as written FDA feedback

Thank you!