U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic: Registration & Listing Requirements for In Vitro Diagnostic Products (IVDs), Including Laboratory Developed Tests (LDTs)

December 3, 2024

Registration & Listing Requirements for In Vitro Diagnostic Products (IVDs), Including Laboratory Developed Tests (LDTs)

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U.S. Food and Drug Administration

Learning Objectives

- Review phaseout policy Stage 2 compliance expectations related to registration and listing
- Identify which establishments need to register
- Explain how user fees are paid
- Discuss how to register an establishment and list devices

Phaseout Policy: Stage 2

Establishment Registration & Device Listing

(21 CFR pts. 607, 807 subparts A-D)

Establishment Registration information provides FDA with the location of device establishments and all devices manufactured at those establishments.

Device Listing information provides FDA, patients, and providers information on the universe of IVDs on the market.

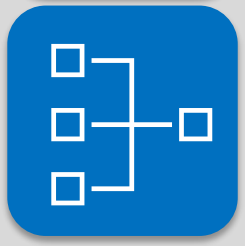
Do I Need to Register?

Establishment

A place of business or other entity under one management at **one general physical location** that performs activities on products subject to FDA regulation

21 CFR 807.3(c); see also 21 CFR 607.3(c)

Single vs Multiple Sites

 **One Geographic Location**	…includes separate buildings within close proximity if the activities in them are closely related to the same business enterprise, under the supervision of the same local management, and are capable of being inspected at the same time.
 **Close Proximity**	• Within a campus setting • Within three miles driving distance of each other • The buildings MUST be within the same State and the same United States Judicial District Court area
 **Quality System**	• Operating under the same Quality Management System

www.fda.gov/media/137463/download

Enforcement Discretion

FDA intends to generally **not** enforce registration and listing requirements for the following tests:

"1976-Type LDTs"

Tests that have the following characteristics common among LDTs offered in 1976

- use of manual techniques (without automation) performed by laboratory personnel with specialized expertise
- use of components legally marketed for clinical use
- design, manufacture, and use within a single CLIA-certified laboratory that meets the requirements under CLIA for high complexity testing

Certain Human Leukocyte Antigen (HLA) Tests for Transplantation

HLA tests that are designed, manufactured, and used within a single laboratory certified under CLIA that meets the requirements to perform high-complexity histocompatibility testing when used in connection with organ, stem cell, and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring or for conducting real and "virtual" HLA crossmatch tests.

Forensic Tests

Tests intended solely for forensic (law enforcement) purposes.

Department of Defense (DoD) and Veterans Health Administration (VHA) LDTs

LDTs manufactured and performed within the DoD or VHA. This policy applies only to LDTs used for patients that are being tested and treated within the DoD or VHA.

Public Health Surveillance Tests

Tests manufactured and offered for use exclusively for public health surveillance

When Do I Need to Register?

Initial

By May 6, 2026

OR

within 30 days of an establishment beginning an activity or putting a device into commercial distribution*

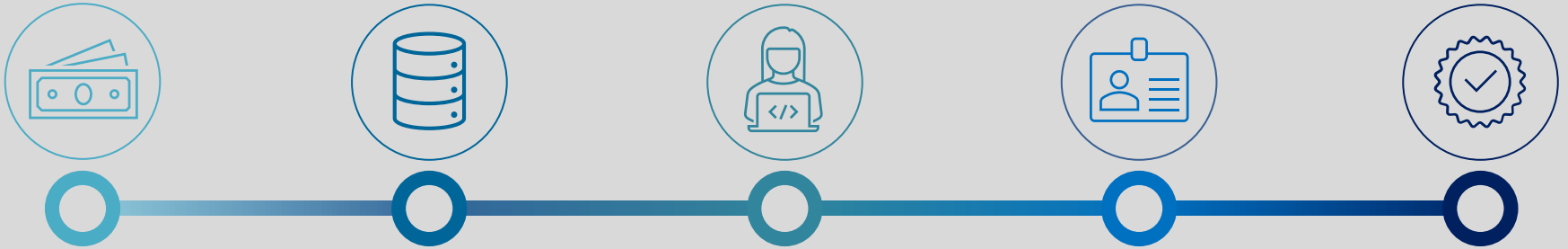
Annual

Complete annually, between October 1 – December 31 of each year

See 21 CFR 807.22 for information on annual registration and when to file updates

***For IVDs offered as LDTs subject to the phaseout policy and introduced on the market after May 6, 2026**

Establishment Registration and Device Listing Steps for Initial Registration



Step 1
Create an account and pay establishment registration user fee in DFUF website

Step 2
Create an account in FURLS

Step 3
Submit initial registration in FURLS/DRLM

Step 4
Create device listing in FURLS/DRLM

Step 5
Review and certify registration info is correct then enter PIN/PCN

Tutorial: www.accessdata.fda.gov/cdrh_docs/presentations/FURLS/story.html

DFUF: Device Facility User Fee Website
FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module
PIN: Payment Identification Number
PCN: Payment Confirmation Number

Pay the Establishment Registration User Fee in DFUF Website

Create an account on the Device Facility User Fee (DFUF) website to pay the Establishment registration user fee: https://userfees.fda.gov/OA_HTML/furls.jsp

Submit your order in the DFUF website and obtain PIN:

- PIN starts with 50xxxxx

PCN will be sent to you by email when payment is processed.

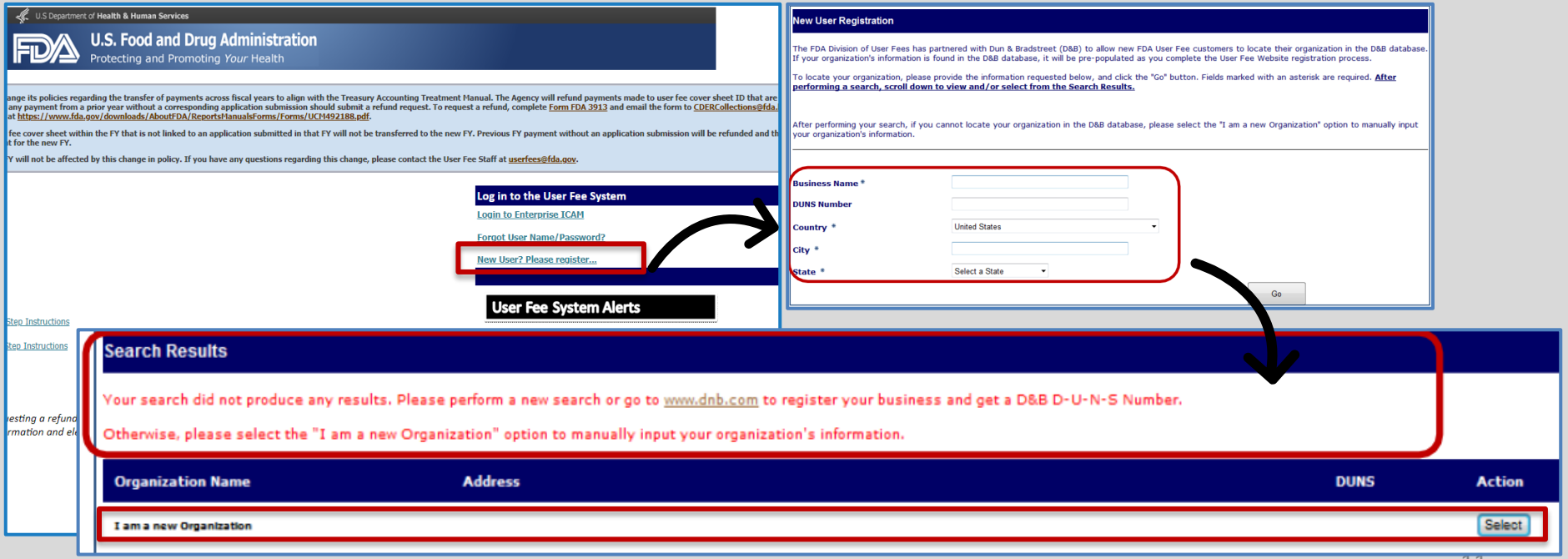
- PCN starts with 25xxxxx

Tutorial: www.accessdata.fda.gov/cdrh_docs/presentations/AnnualFee/index.html

Current Fiscal Year User Fees: www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing
PIN: Payment Identification Number
PCN: Payment Confirmation Number
DFUF: Device Facility User Fee Website

Pay the Establishment Registration User Fee in DFUF Website

https://userfees.fda.gov/OA_HTML/furls.jsp



Pay the Establishment Registration User Fee in DFUF Website

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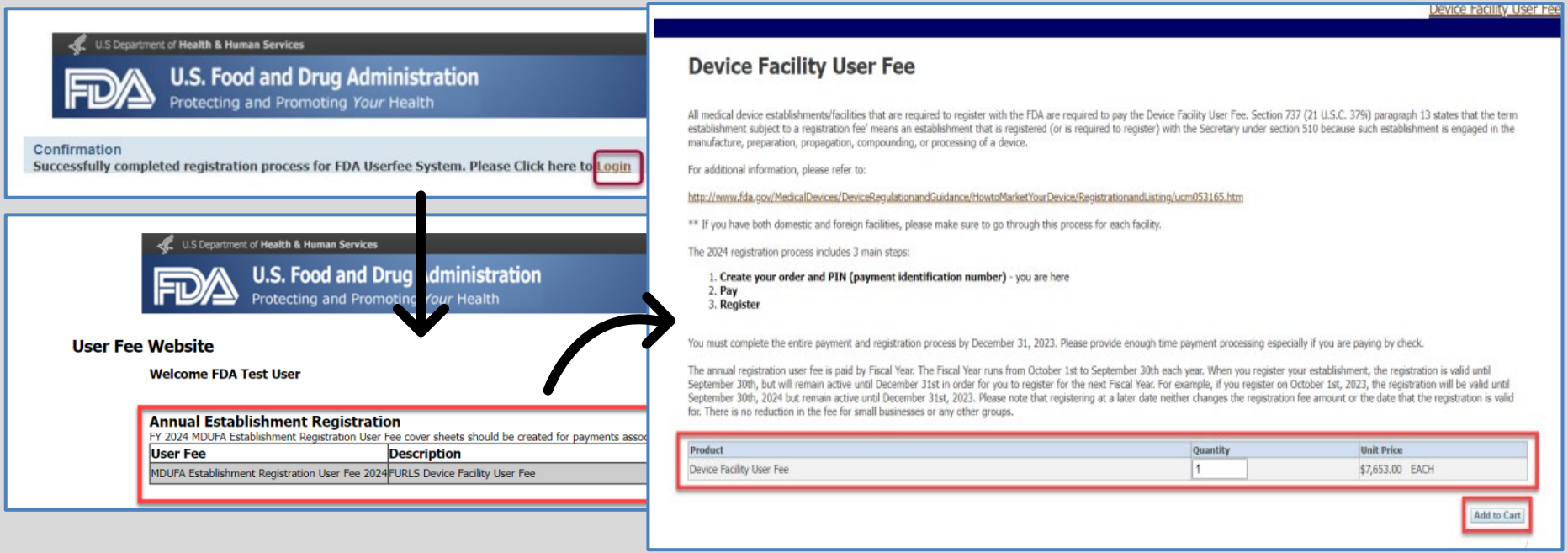

Pay the Establishment Registration User Fee in DFUF Website

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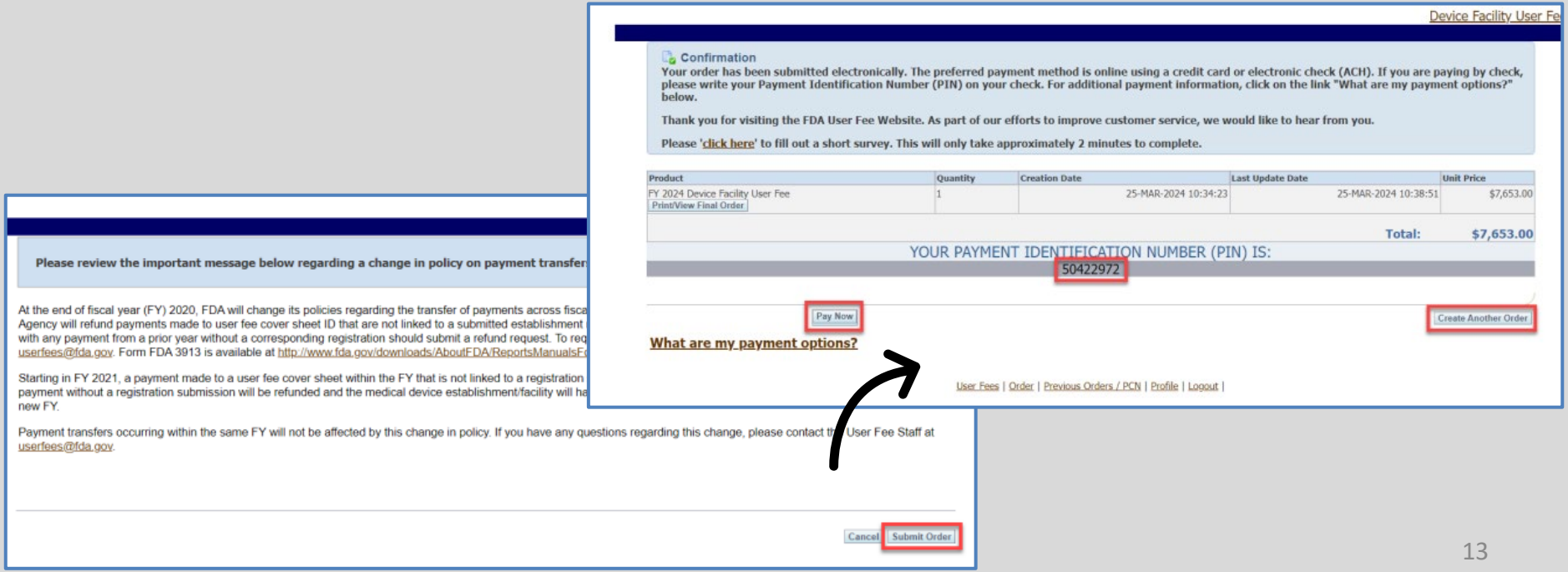


Create an Account in FURLS/DRLM

All establishment registration information is submitted electronically using the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM)

Create an account for FURLS at:
www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1

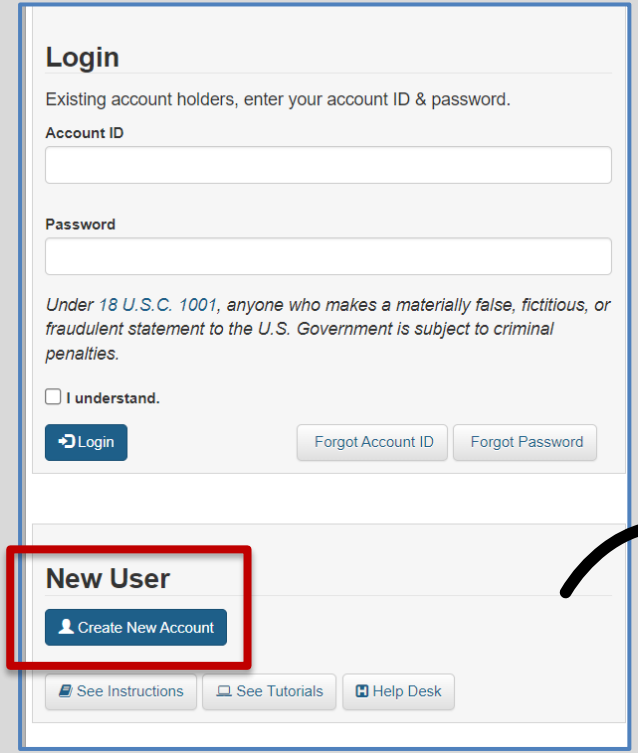
Under New User, click Create Account

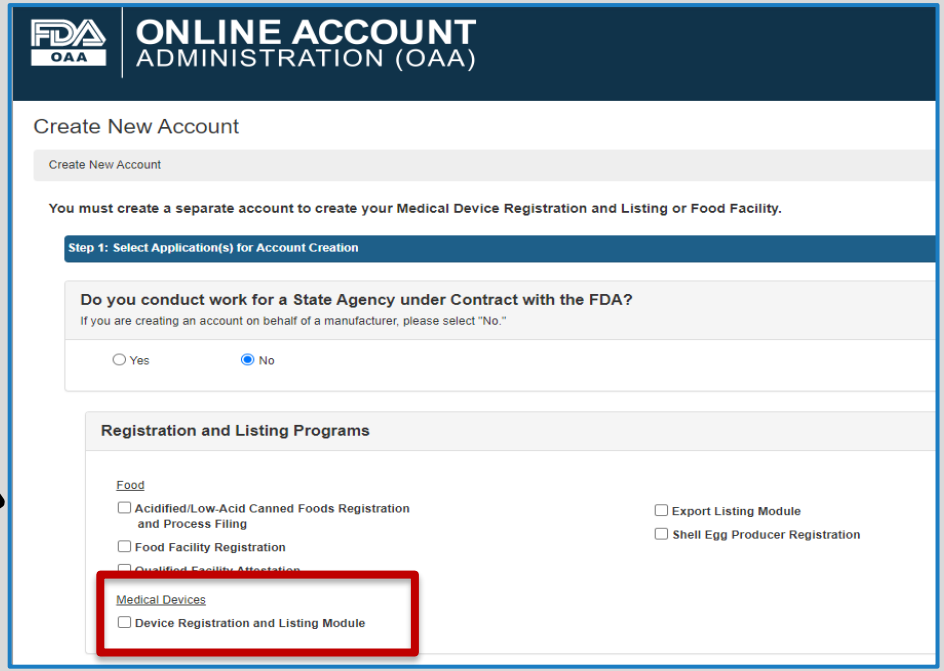
Tutorial: www.fda.gov/food/online-registration-food-facilities/fda-industry-systems-account-management-guide

FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module [within FURLS]

Create an Account in FURLS/DRLM

https://www.access.fda.gov/oaa/logonFlow.htm?execution=e2s1





Create Initial Registration in FURLS/DRLM

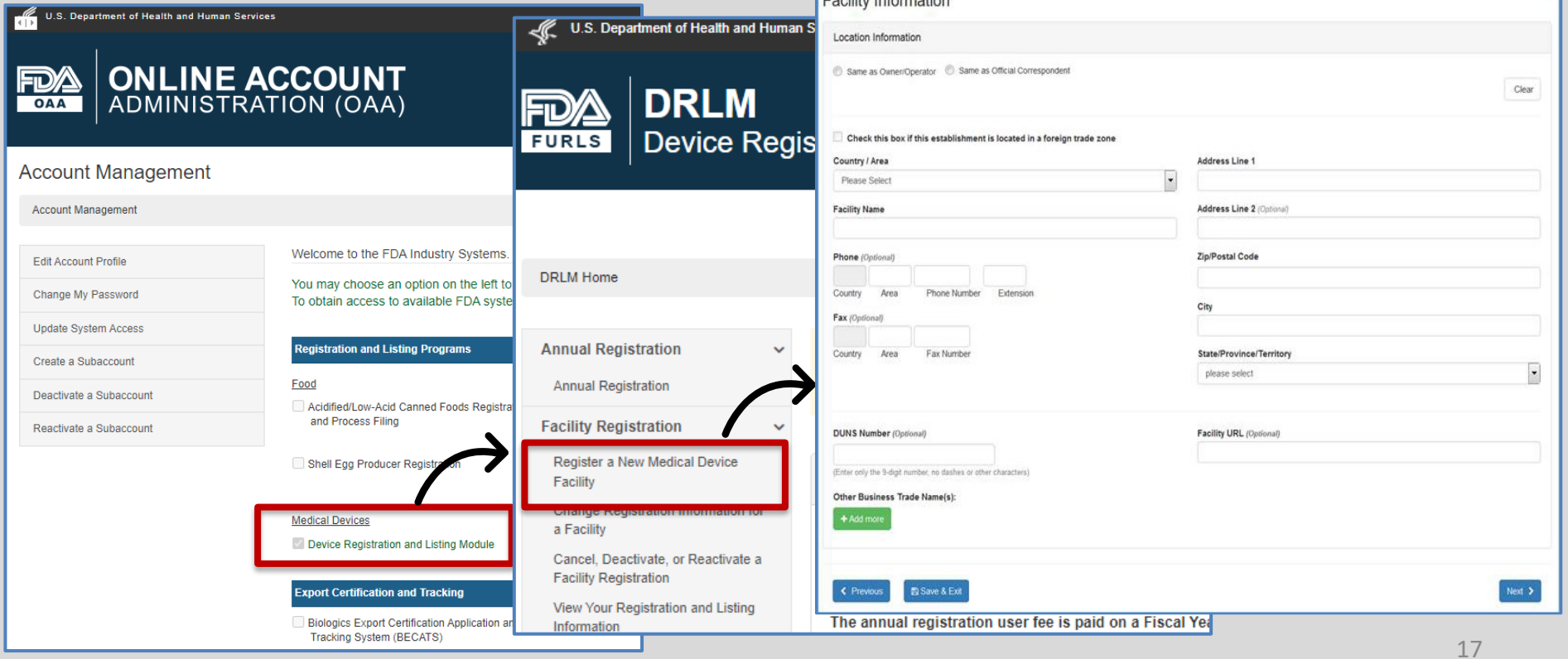
Click on Device Registration and Listing Module. Click on Register a New Medical Device Facility. Provide the required information for the establishment

- Establishment, owner operator, and official correspondent
- Name, address, phone number, and email address for each of above contacts
- Establishment website address, if any
- Trade names used by establishment

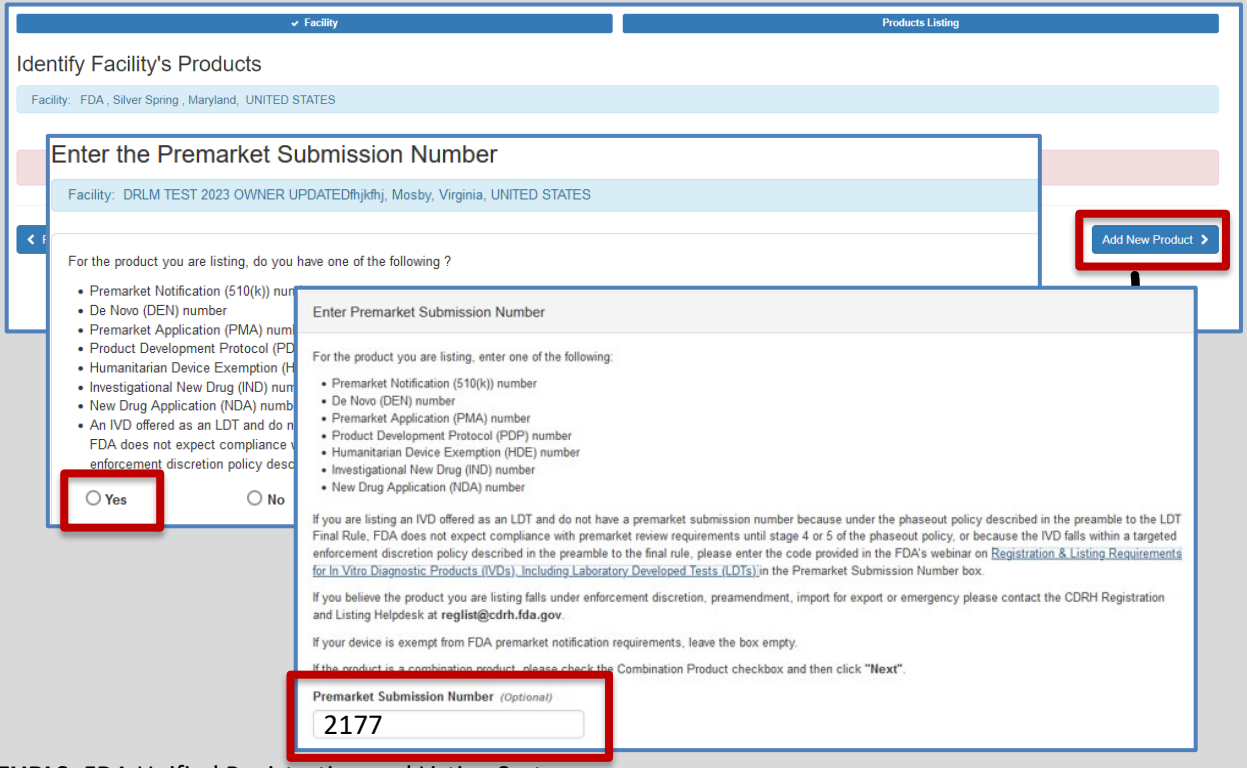
Tutorial: www.access.fda.gov/drlm/help/RegisterANewMedicalDeviceFacility.html

FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module [within FURLS]

Register a New Medical Device Establishment in FURLS/DRLM



Create Device Listing in FURLS/DRLM



If at the time of listing, FDA generally does not intend to enforce compliance with premarket review requirements for the IVD offered as an LDT being listed, enter "**2177**" in the Premarket Submission Number field:

A list of policy specific product codes will be displayed

FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module [within FURLS]

Policy Product Codes

SCE

IVD offered as LDT, first marketed before May 6, 2024, not modified beyond scope described in preamble to LDT Final Rule

Currently marketed in vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that were first marketed prior to May 6, 2024, and not modified following that date or not modified beyond the scope described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCF

LDT, unmet need within an integrated healthcare system

Laboratory developed tests (LDTs) manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system as described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCG

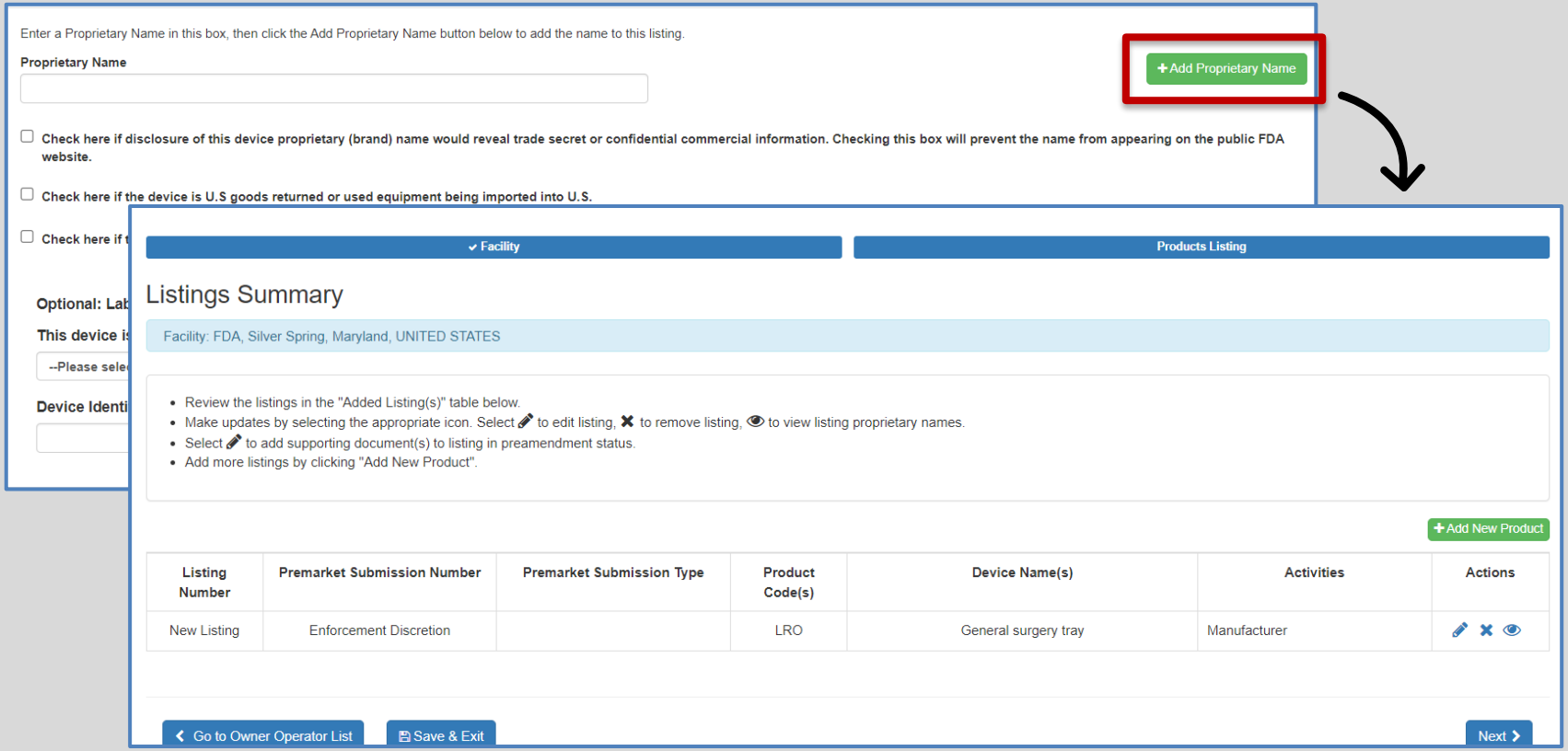
Modified version of another manufacturer's FDA-authorized test within scope described in preamble to LDT Final Rule

When a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meeting CLIA's regulatory requirements to perform high complexity testing modifies another manufacturer's 510(k) cleared or De Novo authorized test, and in compliance as described in section V.C.3 of the preamble to the LDT Final Rule, in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification as described in sections V.C.4 and V.C.5 of the preamble to the LDT Final Rule (89 FR 37286).

Policy Product Codes

SCH	**LDT, approved by NYS CLEP** Laboratory developed tests (LDTs) that are approved by the New York State Department of Health Clinical Laboratory Evaluation Program (NYS CLEP) described in section V.B.2 of the preamble to the LDT Final Rule (89 FR 37286).
SCI	**IVD offered as LDT, not an LDT or under a targeted enforcement discretion policy described in preamble to LDT Final Rule** In vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that are not designed, manufactured, and used within a single laboratory, are within the scope of the phaseout policy and are not subject to a targeted enforcement discretion policy described in the preamble to the LDT Final Rule (89 FR 37286).
SCJ	**LDT, not under a targeted enforcement discretion policy described in preamble to LDT Final Rule** Laboratory developed tests (LDTs) within the scope of the phaseout policy and not subject to a targeted enforcement discretion policy described in section V.B of the preamble to the LDT Final Rule (89 FR 37286).
SCK	**LDT, Non-molecular antisera for RBC antigens when there is no alternative IVD** Non-molecular antisera laboratory developed tests (LDTs) for rare red blood cell (RBC) antigens when manufactured and performed by blood establishments, including transfusion services and immunohematology laboratories, and when there is no alternative in vitro diagnostic product (IVD) available to meet the patient's need for a compatible blood transfusion within the scope described in Section V.B.3 of the preamble to the Final LDT Rule (89 FR 37286).

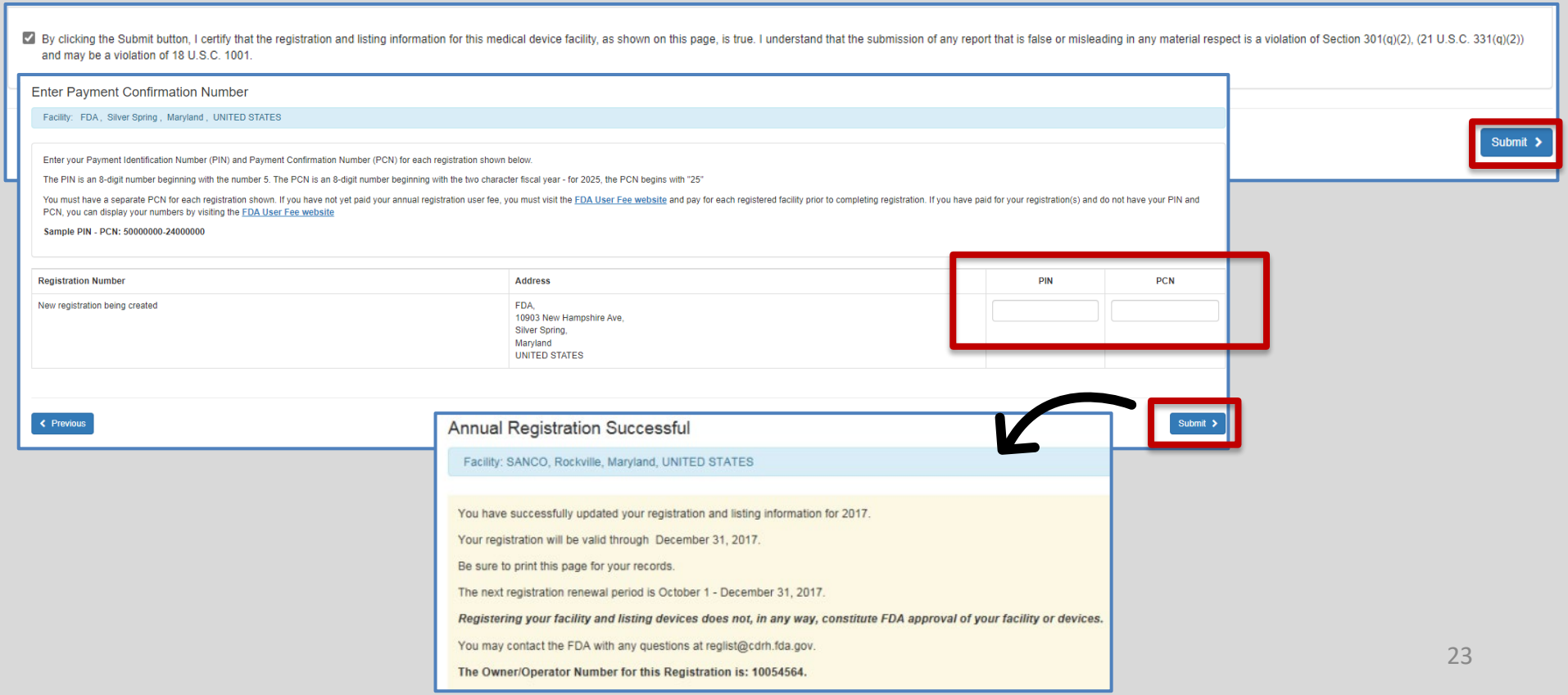
Create Device Listing in FURLS/DRLM



Review and Certify Registration

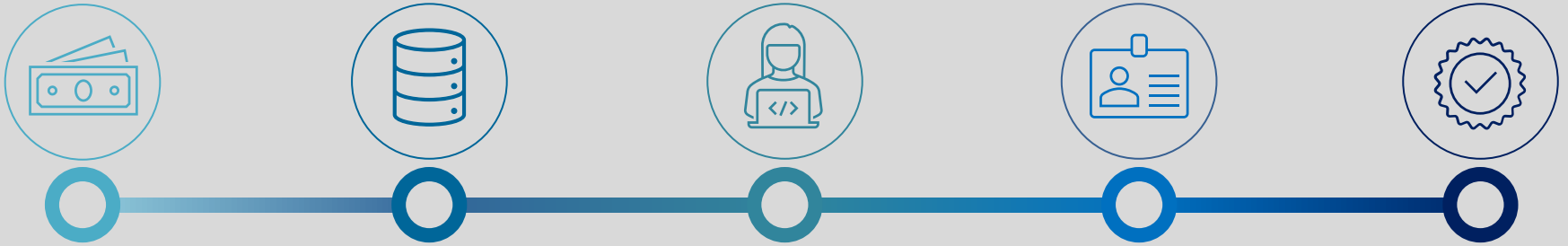
- Review registration information and check box next to “Certification Statement”
- Enter PIN/PCN numbers
- Your owner/operator number will appear in the text of the Registration Confirmation message
- The Official Correspondent (OC) will receive an email confirming that the establishment has been registered

Review and Certify Registration



Establishment Registration and Device Listing

Steps for Annual Registration



Step 1
Log into DFUF website and pay Annual Registration User Fee

Step 2
Log into existing account in FURLS

Step 3
Click on "Annual Registration" and complete registration for the establishment in FURLS/DRLM

Step 4
Edit registration information and/or device listing(s), as needed, in FURLS/DRLM

Step 5
Review, certify and enter PIN/PCN

Tutorial: www.fda.gov/media/107672/download

DFUF: Device Facility User Fee Website
FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module
PIN: Payment Identification Number
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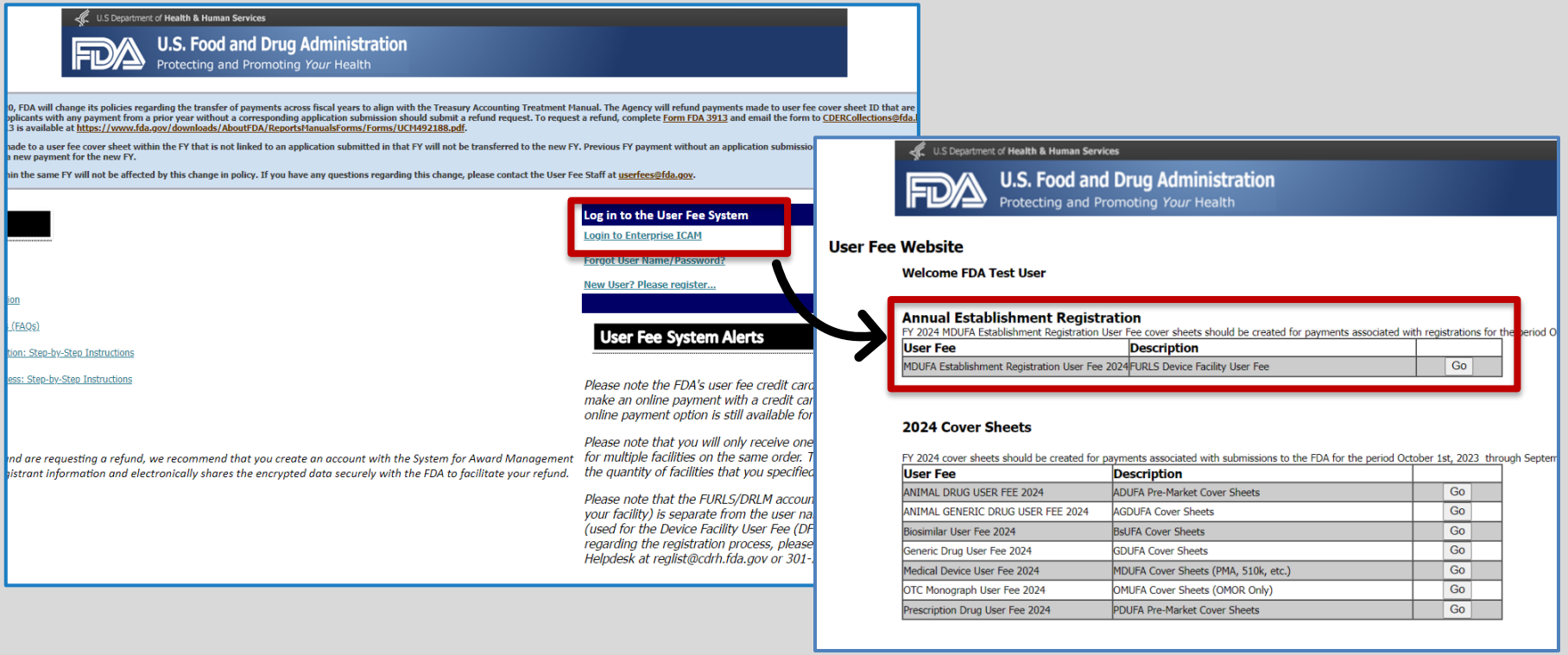
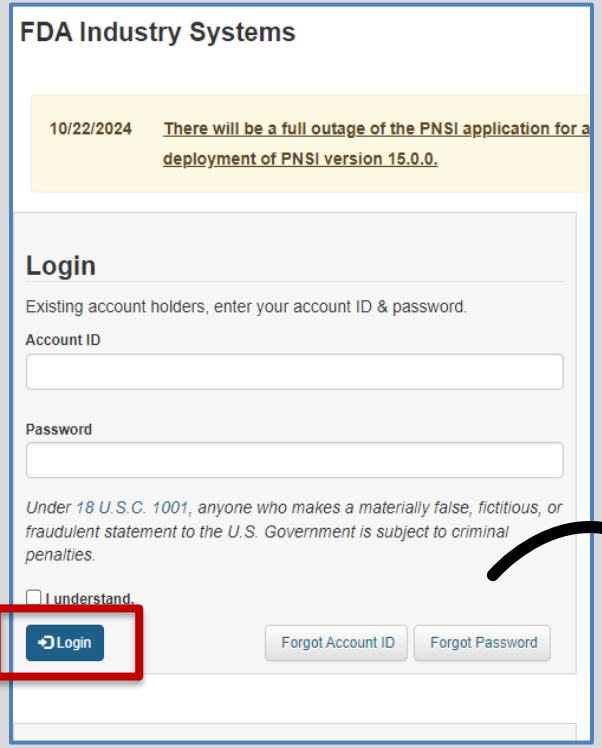
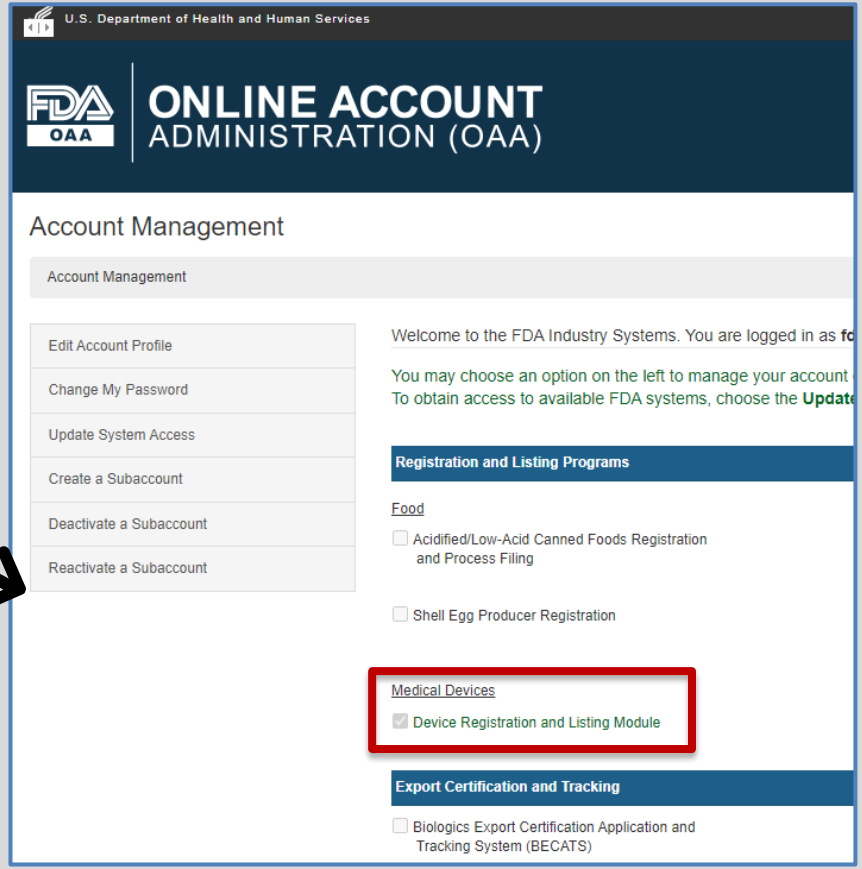
Pay the Annual Registration User Fee in DFUF Website



DFUF: Device Facility User Fee Website

Log into Existing Account in FURLS



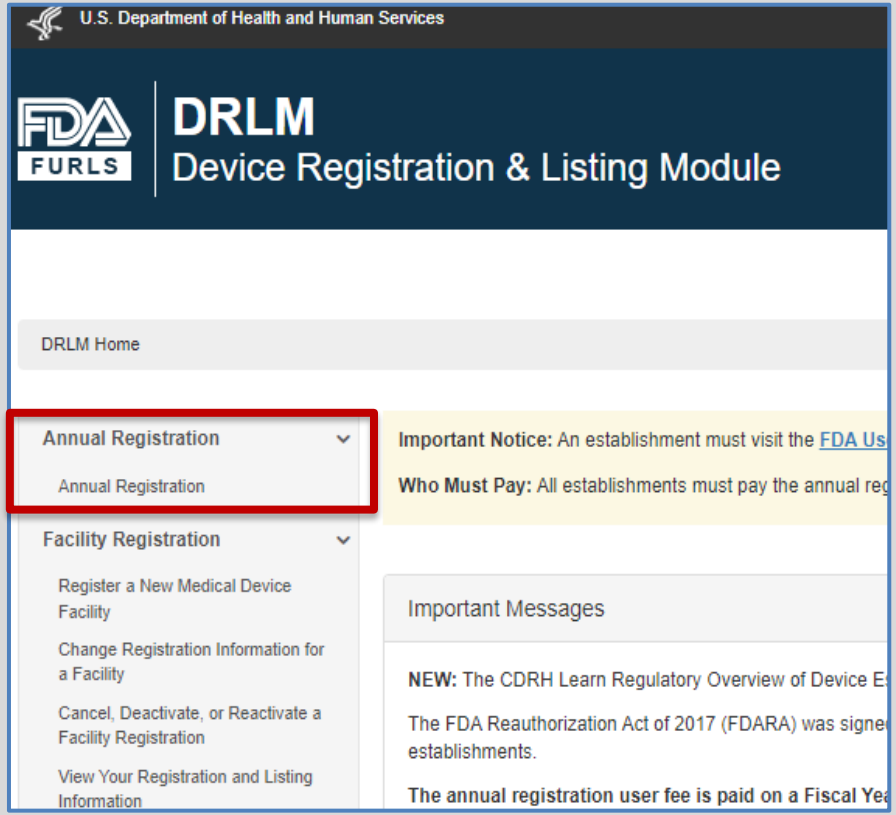


FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module [within FURLS]

Click on Annual Registration to complete the annual registration for the Establishment in FURLS/DRLM

Review your registration and listing information

Make any necessary updates to establishment registration and/or device listing(s)



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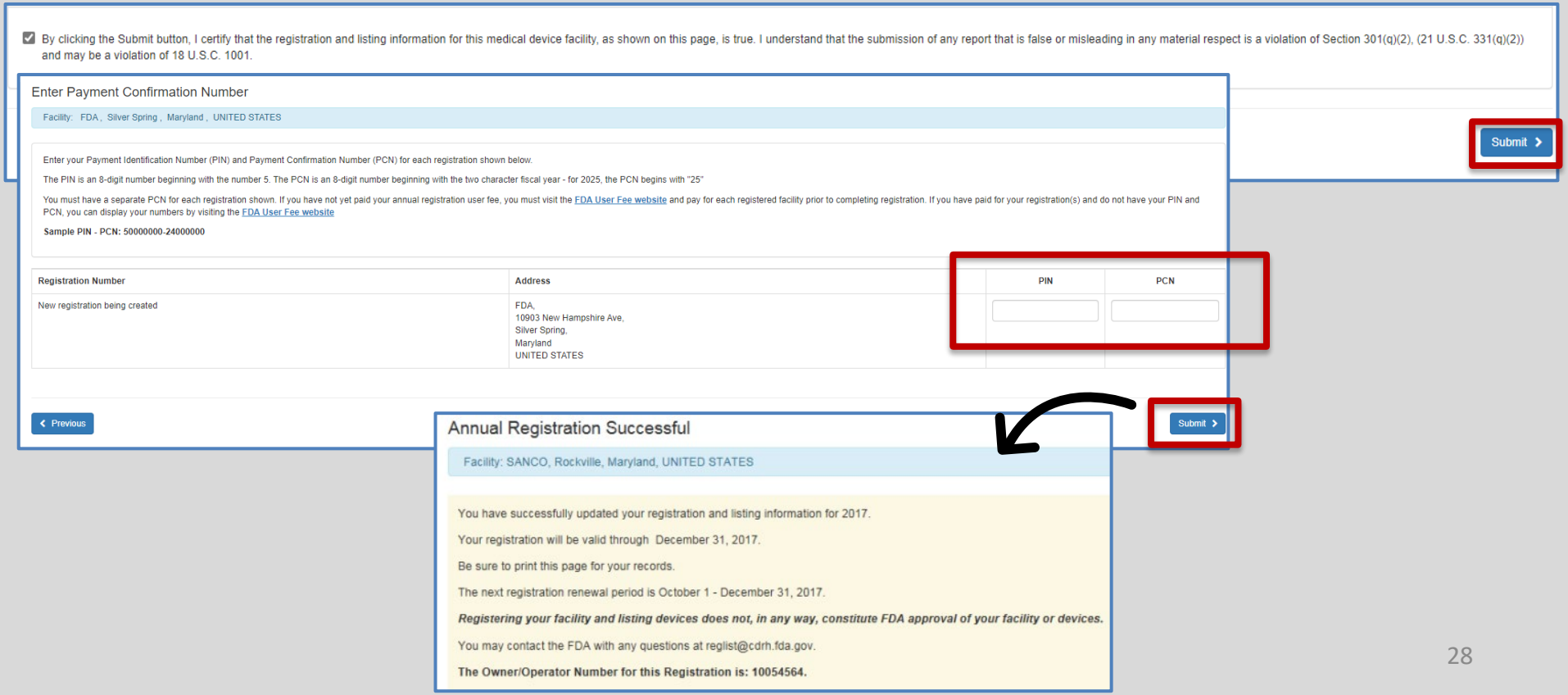
Review and Certify Registration



Registration and Listing Help

For **questions regarding user fees**, please reach out to the User Fee Helpdesk, by e-mail at: userfees@fda.gov

For **general information about the registration and listing process** or assistance with entering your registration and listing information into FURLS/DRLM, please email the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov

For **policy or specific questions about requirements for IVDs offered as LDTs**, please email the LDT Mailbox at LDTFinalRule@fda.hhs.gov

Registration and Listing Summary

Laboratories that manufacture IVDs, including laboratory developed tests, are generally required* to pay the annual registration user fee, and register and list the tests they manufacture

If a firm owns or operates more than one establishment, the firm can create the registration for each laboratory under their owner/operator account

Each IVD offered as an LDT must have its own device listing

**See* preamble to the LDT final rule for targeted enforcement discretion policies

Next Webinar

[Laboratory Developed Tests | FDA]

Date
February 2025

Time
TBD

Topic
TBD

Please submit questions in advance to:
CDRHWebinars@fda.hhs.gov

Resources and References

Slide Number	Resource	URL
4	Final Rule Regarding LDTs	www.federalregister.gov/public-inspection/2024-08935/medical-devices-laboratory-developed-tests
5,8	Code of Federal Regulations, Part 807	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807
7	Laboratory Developed Tests	www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests
5,8	Code of Federal Regulations, Part 607	www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-607
5,8	Who Must Register, List and Pay the Fee	www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee
6	The OEI Development and Maintenance Procedure (SOP-000051)	www.fda.gov/media/137463/download
9	FURLS Device Registration & Listing Module for Initial Registration	www.accessdata.fda.gov/cdrh_docs/presentations/FURLS/story.html
10	CDRH LEARN: Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website	www.accessdata.fda.gov/cdrh_docs/presentations/AnnualFee/index.html

Resources and References

Slide Number	Resource	URL
11,12,13	DFUF	userfees.fda.gov/OA_HTML/furls.jsp
11,12,13	User Fee System (UFS) User Fee iStore Account Creation Desk Guide	https://userfees.fda.gov/OA_HTML/furls_account_creation.pdf
14	FURLS	www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1
14	FURLS Cover Sheet Creation: Step-by-Step Instructions	https://userfees.fda.gov/OA_HTML/FURLSCScreation.pdf
15	FDA Industry Systems Online Account	www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1
16-23	Register a New Medical Device Facility: Step-by-Step Instructions	www.access.fda.gov/drlm/help/RegisterANewMedicalDeviceFacility.html
16-23	FDA Industry Systems Account Management Guide	www.fda.gov/food/online-registration-food-facilities/fda-industry-systems-account-management-guide

Resources and References

Slide Number	Resource	URL
16-23	How to Register and List	www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list#initial
16-23	CDRH LEARN: Device Registration and Listing: An Introduction – Part 1	https://fda.yorkcast.com/webcast/Play/0d11c844da704628a6ea85b06b1dbe8b1d
16-23	CDRH LEARN: Device Registration and Listing: An Introduction – Part 2	https://fda.yorkcast.com/webcast/Play/764ece0cf29b47b48ac5c2e6cd765a0b1d
16-23	FURLS Device Registration and Listing Module for Annual Registration	www.fda.gov/media/107672/download
16-23	FURLS Device Registration and Listing Module for Initial Registration	www.accessdata.fda.gov/cdrh_docs/presentations/FURLS/story.html
16-23	DEVICE ADVICE: Device Registration and Listing	www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing
24-28	FURLS Device Registration & Listing Annual Registration	www.fda.gov/media/107672/download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Previously Submitted Questions

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- **Presentation and Transcript will be available at CDRH Learn**
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- **Additional questions about today's webinar**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHEvents


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