CDRH Portal Overview and Feature Walkthrough

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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Center for Devices and Radiological Health
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Learning Objectives

- Describe the purpose of the CDRH Portal
- Discuss what submissions can be uploaded through the CDRH Portal
- List what submissions can tracked in the CDRH Portal

What is the CDRH Portal?

The CDRH Portal (Customer Collaboration Portal) is **secure website** that allows industry to:

- **Upload** CDRH-led premarket submissions to CDRH
- **Track the progress** of supported premarket submissions

Uploading Through the Portal

Uploading Through the Portal

- **Anything that that is mailed** to the CDRH document control center (DCC) can be uploaded through the Portal
- Uploads are **limited to 4GB**
- Nothing physical need be sent for a file uploaded through the Portal

Uploading Through the Portal

- **Cover letters** should be included in **PDF format** (does not apply to eSTAR)
- There are no file name requirements, but logical file names that help our DCC identify the file
  - Example: K23#### AI response.zip
- Uploads completed after **16:00 ET will be processed the next normal business day**

Uploading Through the Portal

- Submit as **1 single file**
- Starting on **1 Oct 2023**, all **510(k)s** must be submitted in **eSTAR format** through the Portal

Tracking a Submission

- Portal currently supports the progress tracking:
  - 510(k)s: Traditional, Special, Abbreviated 510(k)s
  - Pre-Submissions
- Tracking of a submission is initially only available to the Official Correspondent on record
- Official Correspondent can share the progress tracking with other Portal users

HELP

How Do I Find Out More?

- **Portal Help** (inside the Portal)
  - Answers to many commonly asked questions
  - Instructions on how to use features such as the progress tracking "Share with others"
- **Anyone can self-register** for a Portal Account
- To find links to the Portal and to the self-registration page, do a web search for "**FDA send and track**"

Portal Help

Welcome, The Peep Army

Your premarket medical device reviews

ID	Received date	Progress	Type	Track	Goal date	Days	More info

You have no premarket medical device reviews yet.

Your sent submissions

You haven't sent anything yet. Send a submission, or [illegible]t + in the main navigation.

Send your submission before 16:00 ET on a b[illegible]ess day for us to process it the same day.

Talk to us

What did you thi[illegible] this experience? Share your thoughts at CCP@fda.hhs.gov.

If you just [illegible] submission, we will send you an email confirming this upload soon. We will also s[illegible]e Official Correspondent an email update about their submission's status within 1 b[illegible]s day. If these emails are not received, please contact CCP@fda.hhs.gov.

[illegible]eed more help? Visit our self-help or tell us what you need at CCP@fda.hhs.gov.

Do you research website data security? Read the HHS Vulnerability Disclosure Policy.

FDA

FDA CDRH Portal

Common questions

What's new

Back to CCP Dash

Common questions

re there any file size limitations for uploads?

Yes, Port loads should be below 4GB. If you cannot find a way to make your submission smaller than 4GB, you may ship it to the CDRH document control center.

Read full article

Are there file naming requirement for uploads?

Currently there are no file name requirements. However, the following recommendations will lessen the chances of complications during the processing of the uploa

- Use a file name that includes your submission number, if known, or plain language descriptive name such as "Quokka Medical 510k.zip" or "K25#### additional info
- Avoid special characters and foreign language characters when possible.

Read full article >

Do I need to send anything physical if I use the Portal?

Welcome, The Peep Army

Your premarket medical device reviews

ID	Progress		Type	Track	Goal date	Days	More info
K222801		On Hold	510(k)	Traditional	Tue Jun 20, 2023	response due in 84 days	—

Your sent submissions

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Submission Tracker

Traditional 510(k)

K230030

The Rubber Duck Brigade

Spiny enchilada despiner

FDA Office
OHT2

FDA Division
DHT2A

FDA Team
THT2A3

FDA Reviewer
Nelson Anderson

Progress

Reviewing: We are reviewing this medical device.

Your Reviewer will contact you if we need more information.

Tue Feb 28, 2023
Official start

Mon May 29, 2023 | in 62 days
MDUFA decision

Refer to FDA letters for formal descriptions and details.
Future dates are estimates based on MDUFA performance goals.
Day counts exclude days on hold. All records are updated overnight.

- ○ Mon May 29, 2023 | in 62 days | Final decision (estimated): We intend to finish our review of this medical device.
- ○ Sat Apr 29, 2023 | in 32 days | Substantive Interaction: We will decide if you can supply us with more information without a hold.
- ● Mar 21, 2023 | day 21 | We did not have time to confirm the material is complete but we will review its content in-depth.
- ● Feb 28, 2023 | We confirmed your user fee payment.
- ● Feb 28, 2023 | We confirmed your eCopy.
- ● Feb 28, 2023 | We received your request to review this medical device.

Service time

28 days since official start, excluding holds

28 total days spent since official start

0 days on hold since official start

62 days left to meet our overall time estimate

Official correspondent's contact info

Applicant
The Rubber Duck Brigade

Phone
--

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Welcome, The Peep Army

Your premarket medical device reviews

Your sent submissions

Talk to us

Your sent submissions

Peep Army eCopy.zip
eCopy · **Sent to FDA** · Sent Jan 6, 2023 11:34 ET

Thump Keg eSTAR.pdf
eSTAR · **Sent to FDA** · Sent Jan 6, 2023 11:31 ET

Welcome, The Peep Army

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	Progress		Type	Track	Goal date	Days	More info
K2228u		On Hold	510(k)	Traditional	Tue Jun 20, 2023	response due in 84 days	—

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Send a submission

Send your submission before 16:00 ET on a business day for us to process it the same day.

Format selection

File se

Format selection

Which format are you using?

For more details about these formats and h

- eSTAR
- eCopy

Next

Contact

DICE@fda.hhs.gov

General questions

OPEQSubmissionSupport@fda.hhs.gov

Submission assistance

CCP@fda.hhs.gov

Website and technical support

Info on sending files

eSTAR

FDA eSTAR homepage

need to send a third-party me or a CDISC
ical file with your eSTAR...

Vie more

y

Copy guidance

ontents of your eCopy .zip can vary. Simple example:
that contains a single PDF. Complex example: a .zip
ontains several PDFs, a "STATISTICAL DATA.zip," and
C FILES.zip."

tional resources

evice advice

Contact

DICE@fda.hhs.gov

General questions

Send a submission

Send your submission before 16:00 ET on a business day for us to process it the same day.

Format selection — File selection — Confirmation — Sent to FDA

Format selection

Which format are you using?

For more details about these formats and how to send them, see the Info panel.

- eSTAR
- eCopy

Next

Send your eCopy

Send your submission before 16:00 ET on a business day for us to process it the same day.

Format selection — **File selection** — Confirmation — Sent to FDA

File selection

Confirm your eCopy complies with FDA's eCopy guidance
Then, compress your eCopy into a ".zip" file.

Drag & drop your single ".zip" file here, or browse for it.

Cancel submission

Back

Send your eCopy

Send your submission before 16:00 ET on a business day for us to process it the same day.

Format selection — **File selection** — Confirmation — Sent to FDA

File selection

510(k) Submission.zip 76% Stop upload

Cancel submission | Select a different file | Send

Send your eCopy

Send your submission before 16:00 ET on a business day for us to process it the same day.

Format selection — File selection — Confirmation — Sent to FDA

Confirmation

60MB eCopy.zip — Ready to send

Cancel submission | Select a different file | Send

Send your eCopy

Format selection — File selection — Confirmation — **Sent to FDA**

U.S. FOOD & DRUG ADMINISTRATION

Hi Nelson,

We are processing the submission sent Peep Army eCopy.zip.Jan 6, 2023 11:34 ET. The Official Correspondent for the submission will be updated within 1 business day. If the Official Correspondent hasn't heard from us, contact CCP@fda.hhs.gov.

FDA Center for Devices and Radiological Health

Knowledge Check #1

Which of the below submission types **cannot** be uploaded through the CDRH Portal?

1. 510(k)
2. PMA
3. Small business certification request
4. Master file

Knowledge Check #2

Which of the following submission types can be tracked in the CDRH Portal?

1. PMA
2. IDE
3. Pre-Sub

Summary

- The CDRH Portal can be used to track the progress of:
  - 510(k)s (Traditional, Abbreviated, Special)
  - Pre-Submissions (Written feedback, Meeting request)
- Submissions that can be mailed to the CDRH document control center can also be uploaded through the CDRH Portal

Questions