

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

U.S. Food and Drug Administration



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**”

Welcome, The Peep Army

Your premarket medical device reviews

ID	Received date	Progress	Type	Track	Goal date	Days	More info
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You have no premarket medical device reviews yet.

Your sent submissions

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

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

Talk to us

What did you think of this experience? Share your thoughts at CCP@fda.hhs.gov.

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

Need 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](#).

Portal Help

The screenshot shows the FDA CDRH Portal interface. On the left is a dark blue navigation sidebar with the FDA logo and the text 'CDRH Portal'. It contains two menu items: 'Common questions' and 'What's new'. The main content area has a light blue header with the text 'Common questions' and a link 'Back to CCP Dashboard'. Below this, the first question is 'Are there any file size limitations for uploads?'. A red arrow points from the 'Common questions' menu item to this question. Another red arrow points from the 'What's new' menu item to the 'Are there any file size limitations for uploads?' question. The answer to this question states that uploads should be below 4GB and provides a link to 'Read full article'. The second question is 'Are there file naming requirement for uploads?'. The answer states there are no requirements but provides recommendations and a link to 'Read full article >'. The third question is 'Do I need to send anything physical if I use the Portal?'.

FDA CDRH Portal

[Back to CCP Dashboard](#)

Common questions

Are there any file size limitations for uploads?

Yes, Portal uploads 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 upload:

- 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	<div><div></div></div> On Hold	510(k)	Traditional	Tue Jun 20, 2023	response due in 84 days	—

Your sent submissions

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

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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



Welcome, The Peep Army

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Your premarket medical device reviews

ID	Progress	Type	Track	Start Date	Stage	More info
1234567	<div><div></div></div>	123456	Traditional	Thu Jan 26, 2023	Approved (due in 30 days)	...

Your sent submissions

You haven't sent anything yet. [Send a submission](#)...

Send your submission before 10:00 ET on a business day.

Talk to us

What did you think of this experience? Share your thoughts at [https://peeparmy.fda.gov](#).

If you just sent a submission, we will send you an email confirming this upload soon. We will also send the Official Correspondent an email update about their submission's status within 1 business day. If these emails are not received, please contact [1-800-368-7088](#).

Need more help? Visit our [FAQ](#) or call us when you need at [1-800-368-7088](#).

Do you research medical data security? Read the [FDA Information Technology Policy](#).

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



Your premarket medical device reviews

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

Your sent submissions

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Talk to us

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Do you research website data security? Read the [HHS Vulnerability Disclosure Policy](#).



Send a submission

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

Format selection

Format selection

Which format are you using?

For more details about these formats and how to prepare your submission, visit the [FDA eSTAR homepage](#).

☐ 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](#)

You may need to send a third-party message for a CDISC clinical file with your eSTAR submission.

[View more](#)

[Copy guidance](#)

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

[Additional resources](#)

[Device 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

