

CDRH PORTAL

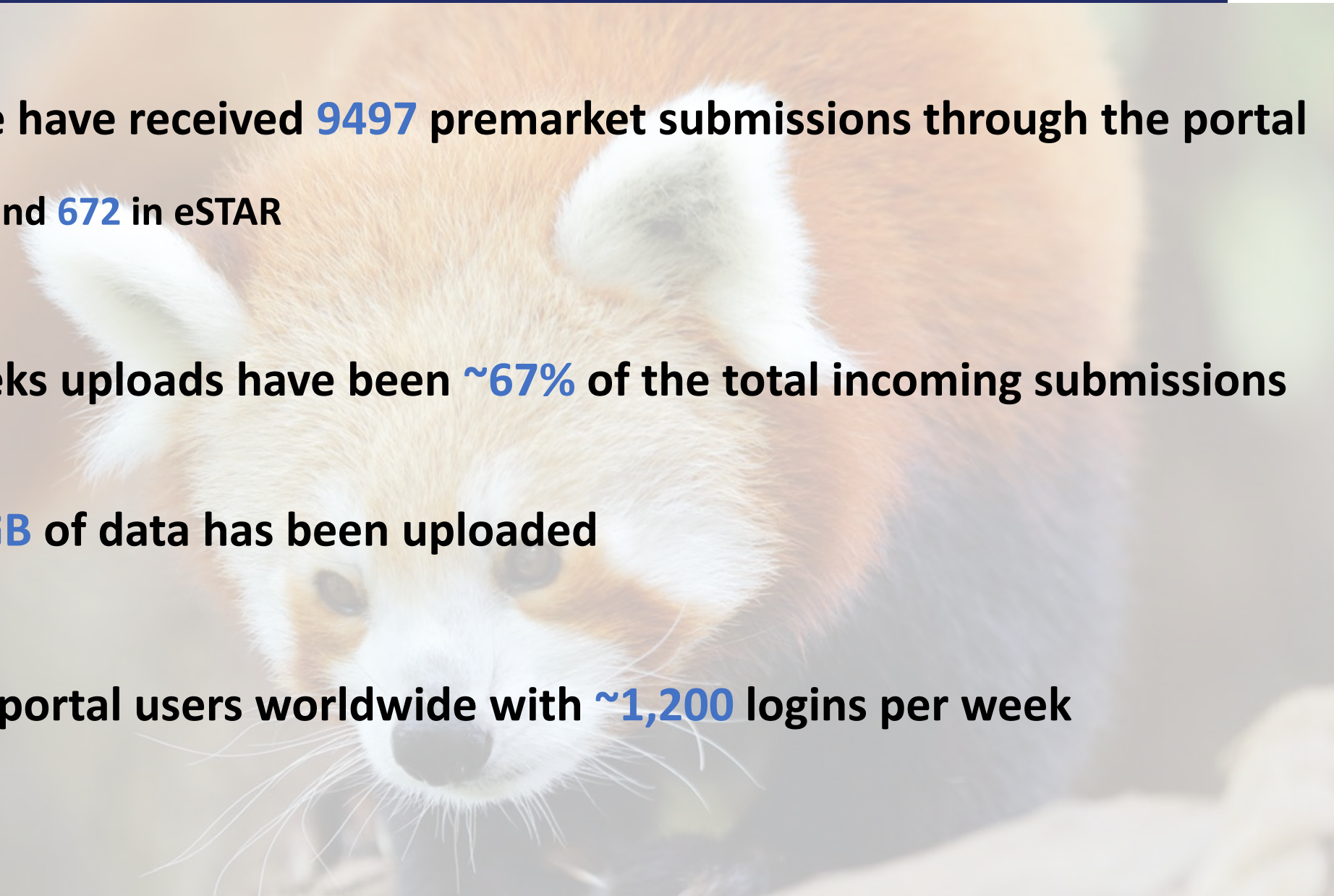
Nels Anderson

CDRH Portal platform owner

CDRH Portal – What is it?

- The CDRH Portal (Customer Collaboration Portal) is secure website that allows industry to:
 - **Upload** CDRH-led premarket submissions to the CDRH document control center
 - **Track** the progress of supported premarket submissions



- As of 24 April we have received **9497** premarket submissions through the portal
 - **8825** in eCopy and **672** in eSTAR
 - The last few weeks uploads have been **~67%** of the total incoming submissions
 - A total of **~500 GB** of data has been uploaded
 - We have **~5,600** portal users worldwide with **~1,200** logins per week
- 

CDRH Portal - Feedback



- ✓ I will start my email by saying FDA's CCP is terrific! Thank you for all of the work that has gone into making this such a simple way to upload and check on the status of FDA submissions!
- ✓ I am writing to express how absolutely impressed I am with this portal. It is easy and convenient.
- ✓ incredibly helpful, informative and easy to use. so much better than the past methods of understanding where we were in the submission process.
- ✓ I love the Portal. Such a delight to use after 34yrs of Fedexing in submissions.
- ✓ This is the best change FDA has made in the 37 years that I have been working in the industry.



CDRH Portal – uploading submissions

- Anything that that is mailed to the CDRH document control center (DCC) can be uploaded through the Portal.
- Portal uploads are limited to **4GB**
 - average Portal upload size is ~54MB
 - 99.9% of the last ~250,000 submissions we have received at CDRH are <4GB
- Nothing physical need be sent for a file uploaded through the Portal.

CDRH Portal – uploading submissions



- **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 (e.g. K23#### AI response.zip) are encouraged.**
- **Each submission should be a single upload*.**
- **Uploads completed after 16:00 ET will be processed the next normal business day.**

CDRH Portal – tracking submissions



- **The Portal currently supports the progress tracking of Traditional, Special, and Abbreviated 510(k)s.**
- **Pre-submissions will be supported in the coming months**
- **The tracking of a submission is initially only available to the Official Correspondent on record. The Official Correspondent can share the progress tracking with other Portal users.**

CDRH Portal – How do I find out more?

- There is no instruction manual
- Portal Help (inside the Portal) has answers to many commonly asked questions. It also has 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](#)”.



ccp@fda.hhs.gov



Demo



Welcome, The Peep Army



Your premarket medical device reviews

ID	Progress	Type	Track	Goal date	Days	More info
K222801	<div style="width: 20%; background-color: red;"></div> On Hold	510(k)	Traditional	Tue Jun 20, 2023	response due in 84 days	--

Your sent submissions

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

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

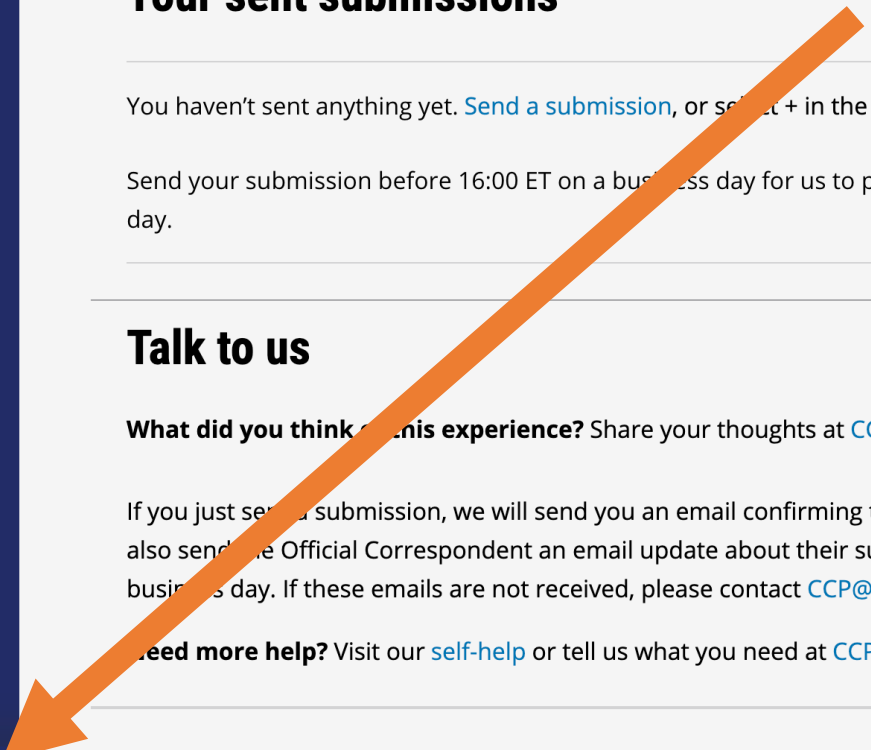
Talk to us

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

If you just 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 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](#).



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?



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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



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Welcome, The Peep Army

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ID	Progress	Type	Track	Goal date	Days	More info
K222801	<div style="width: 10%; background-color: red;"></div> On Hold	5100k	Traditional	Tue Jun 20, 2023	response due in 84 days	—

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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

It's not you, it's us.



We cannot accurately display the information for this item and think it's best to show you this message instead of details that may be incorrect.

We apologize for the inconvenience.

If you have questions, please contact FDA Support Staff at

OPEQSubmissionSupport@fda.hhs.gov.