CDRH Portal Overview and Feature Walkthrough

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Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

Evolving Program

- The CDRH Customer Collaboration Portal is continually being enhanced, so some of the details of this presentation may no longer be entirely accurate.
- See the Portal Help articles (inside the Portal) for the most up-to-date information.

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 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 EST 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

Guidance: Electronic Submission Templated for Medical Device 510(k) Submissions
www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions

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

You have no premarket medical device reviews yet.

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.

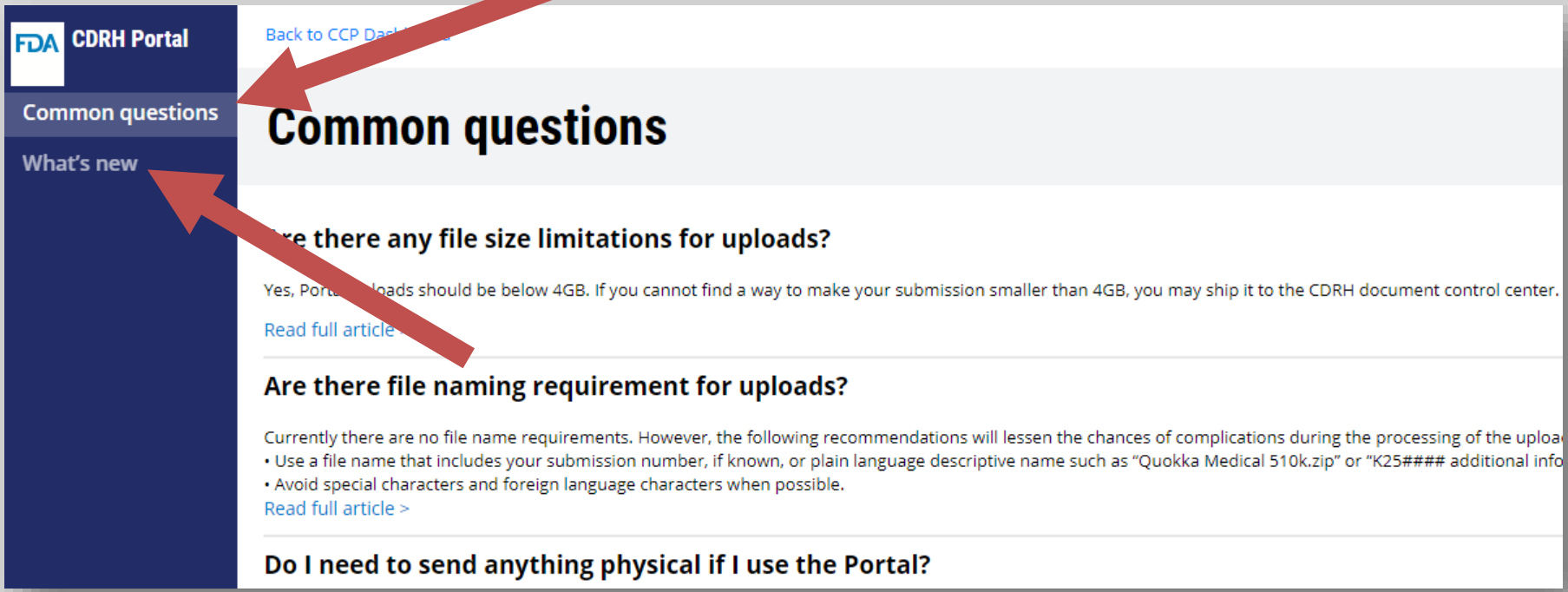
Talk to us

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.


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	--

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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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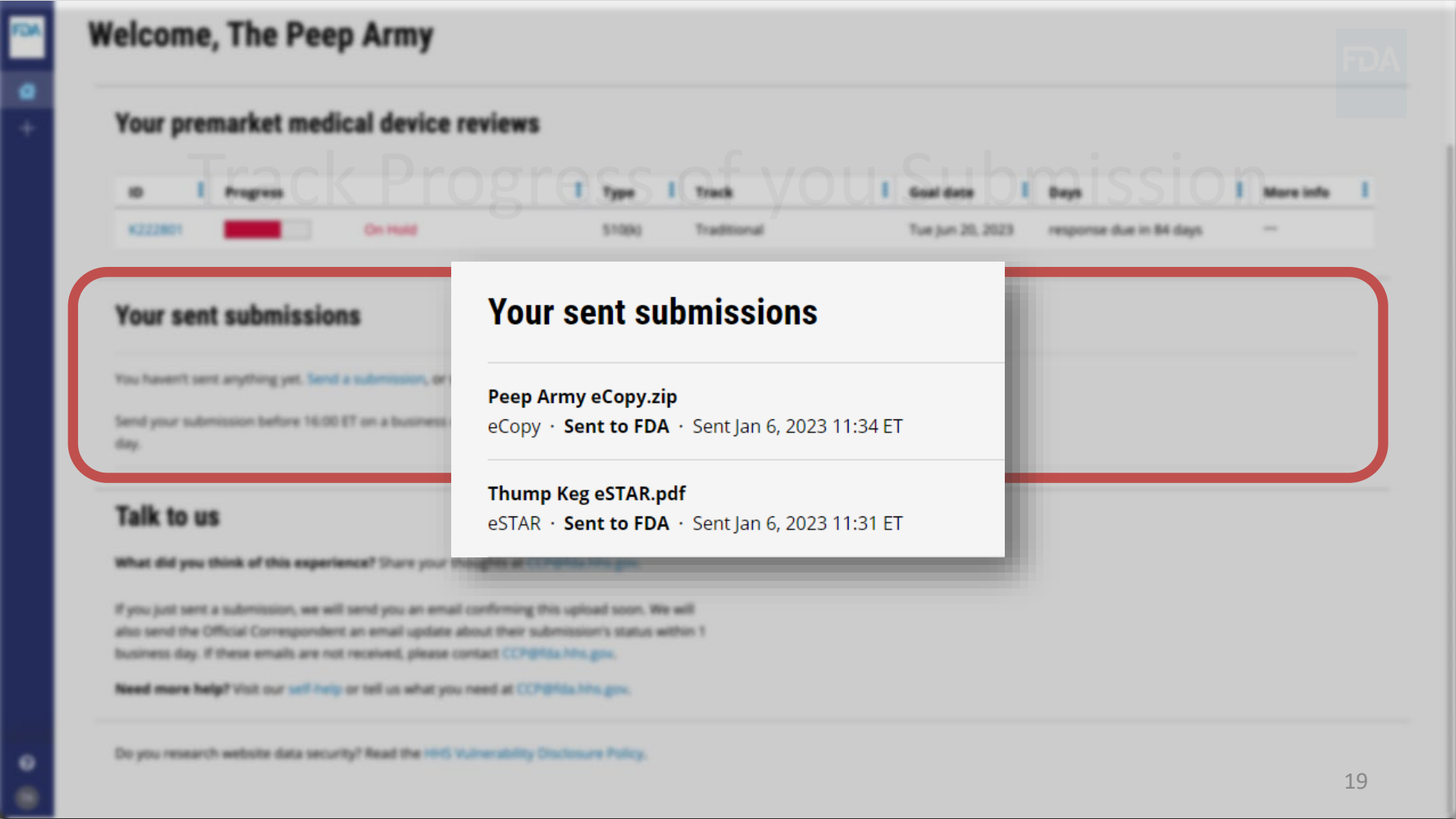
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Track Progress of your Submission
ID
Progress
Type
Track
Goal date
Days
More info
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Do you research website data security? Read the HHS Vulnerability Disclosure Policy.
Your sent submissions
Peep Army 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

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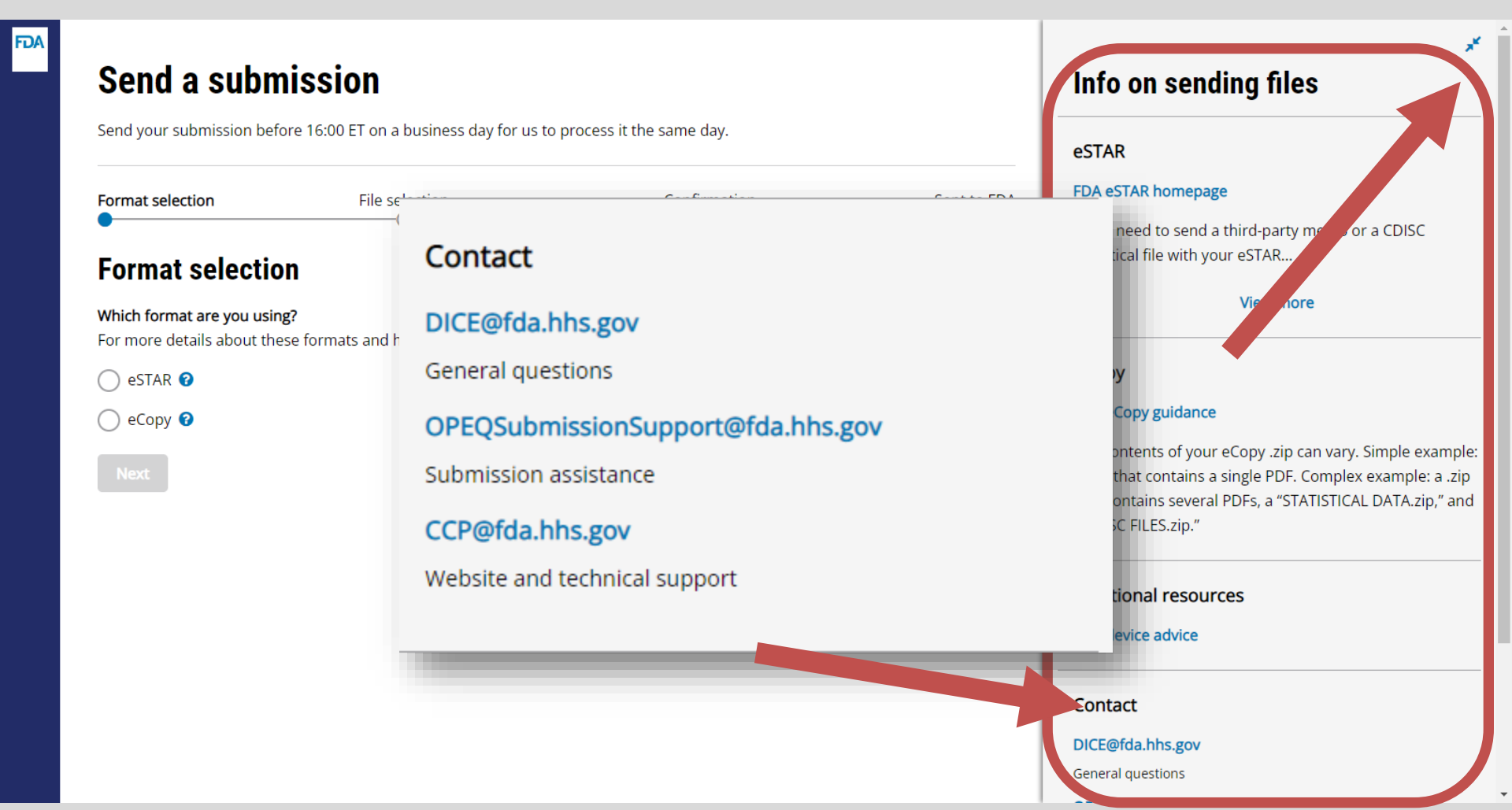

Send a submission
Send your submission before 16:00 ET on a business day for us to process it the same day.
Format selection
File se
Format selection
Which format are you using?
For more details about these formats and h
eSTAR
eCopy
Next
Contact
DICE@fda.hhs.gov
General questions
OPEQSubmissionSupport@fda.hhs.gov
Submission assistance
CCP@fda.hhs.gov
Website and technical support
Info on sending files
eSTAR
FDA eSTAR homepage
need to send a third-party m or a CDISC
ical file with your eSTAR...
Vie ore
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

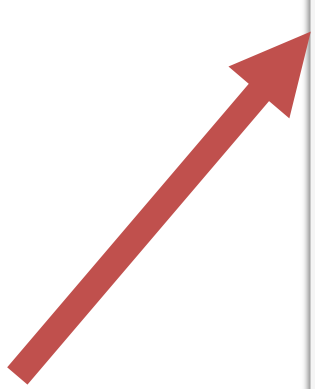
Format selection

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

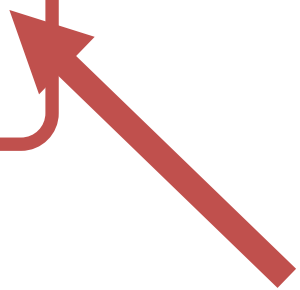
Send your submission before 16:00 ET on a business day for us to process it the same day.

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

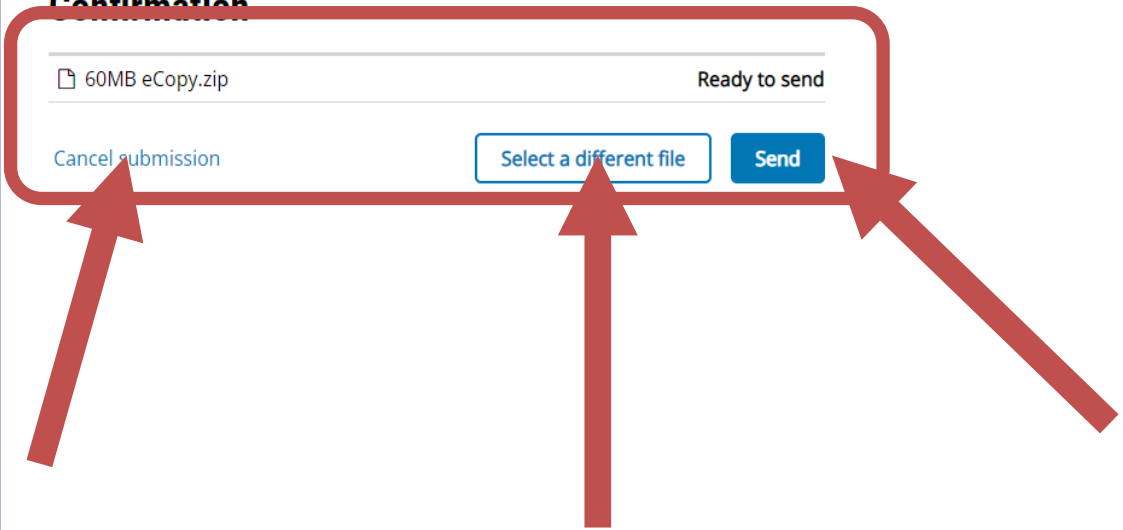
Send your submission before 16:00 ET on a business day for us to process it the same day.

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

Sent to FDA

You have sent your eCopy "60MB eCopy.zip" (Sent Apr 5, 2023 at 18:09 ET)

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.

You can see the upload status of your submission on the home page once it has been refreshed.

This browser tab will close automatically in 2 minutes.

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

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

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1-800-638-2041 or (301) 796-7100 (9 am – 12:30 pm; 1 – 4: 30 pm ET)

Your Call to Action

1. **Use the CDRH Portal to upload your submission to CDRH**
   - Remember: Starting on October 01, 2023, all 510(k)s must be submitted in eSTAR format through the Portal
2. **Track the progress of your submission**
   - For near real-time submission status