

# **CDRH 510(k) eSubmissions Pilot User Guide**

The CDRH 510(k) eSubmissions Pilot User Guide provides information on how to proceed through the CDRH 510(k) eSubmissions Pilot Program. If you have any questions after reading this document, please contact us at [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov).

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# CDRH 510(k) eSubmissions Pilot Steps



Contact the pilot team via email [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov) to let us know you are interested in participating in the pilot. (See page 3)



Download and install eSubmitter [here](#) (See page 3)



Create an Electronic Submission Gateway (ESG) account (if you do not already have one) by following the checklist provided [here](#) (See page 3)



Obtain or export from Internet Explorer a private key (e.g., .pfx file) by following the directions [here](#) (See page 4)



Create a new 510(k) submission (See page 4)



Sign the submission with your private key and package the file into a .zip file (See page 5)



Send the .zip file to the FDA through the ESG. You will receive confirmation emails as it is received and processed (See page 5)



The review of your 510(k) submission will take place as usual. We encourage you to provide feedback on this Pilot (See page 5)

## **NOTE:**

If additional information is requested during the review, use the eSubmitter interface to provide it so that that data included in your eSubmitter submission is up-to-date. FDA encourages interactive review with the reviewer to convey and receive clarifications on the data that are requested/provided.

## Step 1

Contact the pilot team via email [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov) providing the information shown below, to let us know you are interested in participating in the pilot program. To be a part of the pilot, your 510(k) submission must be one that would be reviewed in one of the branches of the Division of Cardiovascular Devices, Division of Neurological and Physical Medicine Devices, Division of Orthopedic Devices, or the Division of Surgical Devices. If you are unsure as to whether your submission would be reviewed by one of those divisions, please contact the [eSubmission pilot team](#).

If your submission does not fall within the scope of this pilot, you are still encouraged to download, evaluate, and comment on the 510(k) eSubmitter Template. Please see the [Frequently Asked Questions](#) section below for more information.

Please remember that we will be accepting only unbundled, traditional 510(k) submissions for classified devices. We are not accepting third party 510(k)s or Combination Products in the pilot program at this time.

### **When you contact us please provide the following information:**

Company Name:

Trade name of subject device:

Proposed product code:

Predicate 510(k)s:

Proposed Indication for Use:

## Step 2

Download and install eSubmitter from [this page](#).

We highly recommend downloading the [User Manual](#) from this same page and reviewing at least Section 3 before you start using the eSubmitter software.

## Step 3

Create an Electronic Submission Gateway (ESG) account (if you do not already have one) by following the checklist provided [here](#). General information about the ESG can be found [here](#).

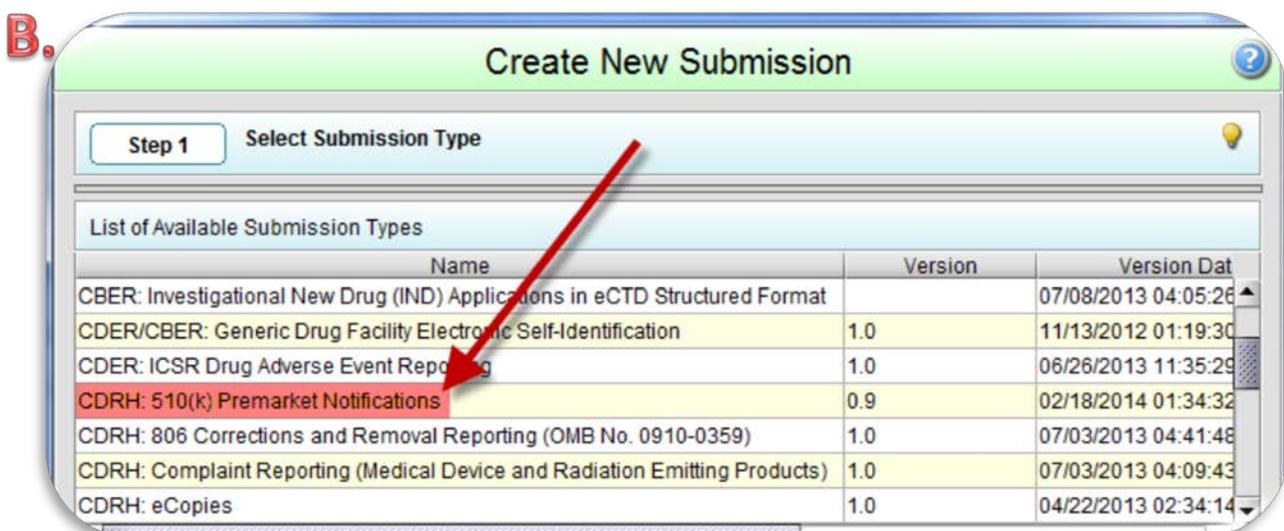
For those applicants who do not have sufficient technical support or time to create a new ESG account, MITRE has offered to assist in the transmission of the 510(k) through the ESG to the FDA free of charge during the pilot. MITRE will ensure that the documentation provided in the submission remains confidential. For those interested in finding out more about this service, please email David Tanenbaum at [cdrh\\_esubmissions@mitre.org](mailto:cdrh_esubmissions@mitre.org).

## Step 4

Obtain or export from Internet Explorer both a public key (for registering your ESG account) and a private key (for signing your electronic submission in eSubmitter) for document submission by following the directions provided [here](#).

## Step 5

Create a new CDRH 510(k) submission in eSubmitter by (A) selecting **Create New Submission...** and then (B) choosing the **CDRH: 510(k) Premarket Notifications** submission type in the eSubmitter interface. The content of “CDRH: 510(k) Premarket Notifications” is the 510(k) eSubmission template on which we would like feedback.



## Step 6

After you have completed entering the information for your 510(k) submission, package the files in eSubmitter into a .zip file, which will include signing the submission with your private key. To learn more about the process for obtaining and using your private key file (.pfx), when packaging the submission in eSubmitter in Step 3 for Digitally Sign Submission, click on the hint and it will provide a link to the Creating Digital Signatures Quick Guide.

## Step 7

Send the .zip file created by eSubmitter through the ESG to the FDA (see Section 4.3 and 4.6 of [the ESG User Guide](#)). You will receive acknowledgement messages in the ESG window as the submission is received and processed. Once FDA receives your submission (presuming the User Fee has been paid and cleared), the review of your 510(k) submission will begin as per the current FDA workflow.

### NOTE:

Please note that if the user fee isn't paid a couple days in advance, the file may temporarily be put on user fee hold since the payment may not have had time to process. If the user fee is in fact paid, the file will be taken off user fee hold automatically, and automatically logged in, once the payment is processed.

If you decide to have MITRE submit the file through the ESG for you, you will send the .zip file to MITRE instead of using the ESG.

### NOTE:

If additional information is requested during the review, please use eSubmitter to add to your original submission and re-submit it through the ESG. FDA encourages interactive review with the reviewer to convey and receive clarifications on the data that are requested/provided

## Step 8

We would appreciate any feedback you have regarding the 510(k) Template in eSubmitter as well as the eSubmission Pilot in general. You can submit your questions, comments or feedback to us by email at [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov).

# Frequently Asked Questions

## 1. What do I do if I am stuck on one of these steps and need help?

Please email us at [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov) and we will respond as quickly as we can. This email address is for any and all questions and help requests regarding the pilot.

## 2. How do I provide official feedback on the pilot program?

Please send us feedback by email to [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov)

## 3. If my 510(k) submission is not in the scope of the pilot program, but I still want to evaluate and comment on the CDRH 510(k) eSubmitter Template, can I do that?

Yes! We encourage all interested parties to download the eSubmitter software which contains the CDRH 510(k) Template (see steps 2 and 5).

Please note that the eSubmitter program is the front end software only for this pilot. We understand that it is a bit dated and not the most user friendly software. Any production system for fully electronic submission of 510(k)s that might come about in the future would not be using the eSubmitter program, but would still use the content of the 510(k) template.

## 4. Will submitting a 510(k) as part of the pilot affect the review of it by the FDA in any way?

No. Once your 510(k) submission is received by the FDA, it will be reviewed in the normal 510(k) workflow of the respective branch.

However, please remember that during the review, updated data and documentation should be submitted as an amendment (or a supplement if responding to deficiencies) using eSubmitter and the ESG, and not via email.

## 5. Will participating in the pilot restrict my company from submitting a 510(k) by the current standard method (hard copy and eCopy)?

No. You may submit your 510(k) either electronically, as part of the pilot, or by the current method, and have it not be part of the pilot. All the current MDUFA goals and deadlines will continue to apply regardless of the method you choose. However, we encourage you to submit all 510(k)s that fall within the scope of this pilot through the ESG as part of the pilot program, as the more submissions we receive during pilot, the better the information and feedback we will receive will be.

## 6. How will I know when the FDA receives my 510(k) submission in the pilot?

You will be able to check receipt of your electronic submission through the ESG interface (see the [ESG user guide](#) section 4.3 step 15). You will also receive the normal 510(k) acknowledgement message from the FDA that you currently receive for a normal 510(k) submission.

## 7. Who is MITRE?

MITRE is a not-for-profit organization that operates multiple federally funded research and development centers. MITRE has no commercial interests, no owners, and no shareholders. The federal government uses MITRE to assist with scientific research and analysis, development and acquisition, and systems engineering and integration.

## Links

### **eSub Pilot Website:**

General information – <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm392813.htm>

### **eSubmitter:**

General information - <http://www.fda.gov/forindustry/fdaesubmitter/default.htm>

eSubmitter download - <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>

### **Electronic Submissions Gateway:**

General information – <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

New account checklist - <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

Digital certificates - <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm334781.htm#4>

User guide - <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm334359.htm>