Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). There is no 510(k) form, however, 21 CFR 8071 Subpart E describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

For additional information, please refer to:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm

1) Access the User Fee Website: https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp
2) Review the statement and select the ‘I Understand’ radio button.
3) For users who have an existing user name and password, proceed to Step 4;
   a. If you do not have an existing account, see the FDA User Fee Account Creation: Step-by-Step Instructions for step-by-step instructions on how to create an account. For additional assistance, contact the User Fee Helpdesk at userfees@fda.gov.
4) Enter a valid user name and password.
5) Select the ‘Login’ button.
6) Select the ‘Go’ button next to ‘MDUFA Cover Sheets (PMA, 510k, etc.’).

7) Select ‘Yes’ or ‘No’ to if your company has paid all establishment registrations fees that are due to the FDA.
8) Select the 'Application Details' button.
MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

9) Make the appropriate selections to configure your cover sheet and select ‘Continue’ to proceed.
   a. Select ‘Center for Devices and Radiological Health (CDRH)’ or ‘Center for Biologics Evaluation and Research (CBER)’
   b. Select ‘Premarket notifications (510(k)); except for third party’ for your type of premarket application
10) Once you have verified your selection of the MDUFA Cover Sheet page, select ‘Continue’ to proceed.

***Please note that this example is for ‘Center for Devices and Radiological Health (CDRH)’ and ‘Premarket notification (510(k)); except for third party’.

11) Select the appropriate response to indicate whether you are a small business. If you select ‘Yes’, enter a valid Small Business Decision number. Otherwise select the ‘No’ option.

On the Small Business Waiver page, select ‘Yes’ or ‘No’ if you are a small business.

a. Click here for more information on qualifying as a Small Business with the FDA, or contact Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at dsmica@fda.hhs.gov or (301) 796-7100.

b. If ‘No’ is selected, click ‘Continue’ to proceed.
Small Business Waiver

Please select if you are a small business

☐ Yes ☐ No

If you have selected "Yes" that you are a small business, you have to enter a valid SBD number for the current FDA fiscal year.

Small Business Decision:

If you believe you are a Small Business and would like to qualify for reduced fees, submit a Small Business Qualification Certification. The Small Business Qualification Certification can be found [HERE].

If you qualify, you will receive a Small Business Decisive (SBD) number. You must provide your SBD number on the Medical Device User Fee Cover Sheet at the time of submission to be eligible for reduced fees. FDA will not accept reduced fees without a SBD number and will not refund the difference between the standard fee and the small business fee after the submission has been received.
MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

12) If none of the exemptions are applicable, click ‘Continue’ to proceed without making a selection.

13) Select ‘Proceed’ to review your cover sheet and submit it to the FDA.
14) After arriving at the ‘Draft Cover Sheet’ page, verify the amount and select the 'Next' button to proceed.

   a. Note: you may save the cover sheet by selecting the ‘Save Cover Sheet’ button. You may return to the ‘Draft Cover Sheet’ menu to access your saved draft cover sheet. Select the checkbox under the ‘Delete’ column and select the ‘Delete Selected Draft(s)’ button to delete a draft cover sheet.
15) On the ‘Checkout: Applicant Contact Information’ page, you will see the billing information for this cover sheet. You can change the address by selecting the ‘Change’ button and follow the instructions to update the address. Once the information has been verified and is accurate, select ‘Next’ to proceed.
MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

16) Review and verify your information, and select the 'Submit Cover Sheet to FDA' button to obtain your Payment Identification Number (PIN).
MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

17) A unique User Fee PIN will be generated with your cover sheet upon submission. Please note that your completed cover sheet is your invoice. To obtain an invoice copy for your records, select on the 'Print/View Final Cover Sheet' button on the ‘Confirmation’ page.

Once you submit your cover sheet and obtain your PIN, you may pay online by selecting the 'Pay Now' button.

You can create and submit another MDUFA cover sheet by selecting the ‘Create Another Cover Sheet’ button.

Note: You can submit payment online by credit card or Automated Clearing House (ACH) electronic check (eCheck), by paper check or by wire/bank transfer. There is a credit card payment limit of $24,999.99. Any payment above the limit will need to be paid using another payment method. The preferred payment method is online. If you prefer to pay via check or wire transfer, please write the PIN on the check or include the PIN with your wire transfer payment. FDA will not be able to process your payment correctly without your PIN.

If you have any further questions about the cover sheet creation process, please contact the User Fee Helpdesk at userfees@fda.gov.

Last Updated: September 28, 2017