**Administrative Documentation**

*【Certain forms may require an Adobe Self-Signed Digital ID. You may alternatively answer questions such that you can attach wet signed scanned forms (e.g., by stating you aren’t a responsible party for the applicant). Use the link below for directions, and be sure to choose the “New PKCS#12 Digital ID File” instead of “Windows Certificate Store” when prompted.*

*Resources*

*Adobe Digital IDs*

*<https://helpx.adobe.com/acrobat/using/digital-ids.html#create_a_self_signed_digital_id>*

*】*

1 General Summary of Submission/Executive Summary

*【We recommend that you provide an executive summary of the submission, which should include a concise description of the device, including the indications for use and technology, and a concise summary for any performance testing in the submission. If this is a 510(k), it should also include a comparison to the predicate device(s).*

*Note that FDA considers this summary optional.】*

2 Financial Certification and Disclosure Statement (Form FDA-3454 and/or 3455)

*【This is only required (according to 21 CFR 54.4) when clinical data are provided. Please refer to the guidance document entitled “Financial Disclosure by Clinical Investigators” for more information. Links to these forms are provided below.*

*Resources:*

*21CFR 54.4*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=54.4>*

*Guidance:“Financial Disclosure by Clinical Investigators”*

*Form FDA-3454*

*Form FDA-3455*

*】*

3 Clinical Trials Certification Form (Form FDA-3674)

*【Please be sure you electronically sign the Truthful&Accurate Statement below.*

*We recommend that you keep an unsigned copy of your eSTAR. This will simplify the process for making changes to this eSTAR, if you need to update it to address Additional Information requests later. If you need to make changes to a signed copy, and the original signatory is no longer available to clear the signature to allow changes, you may contact use at DICE@fda.hhs.gov for directions on how to resolve this.】*

4 Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.

5 Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.

*【Directions on completing the MDUFA User Fee form can be found at the MDUFA Cover Sheet website. The standard and small business fees for a premarket submissions are updated annually on or about August 1st. More information about user fees, as well as the cost to submit your submission, can be found at the Medical Device User Fees (MDUFA) website.*

*If an accredited Third Party Review Organization (3P510(k) Review Organization) will be submitting this eSTAR, please attachment a statement stating this here instead of the MDUFA User Fee Form.*

*Resources*

*MDUFA Website*

*<https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/medical-device-user-fees>*

*MDUFA Amendments Website*

*<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2017-mdufa-iv>*

*MDUFA Coversheet*

*<https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp>*

*MDUFA Coversheet Website*

*<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-cover-sheets>*

*】*

6 Please enter in the User Fee Payment Identification Number.

*【The User Fee Payment ID must adhere to the following format:*

*- two letters,*

*- followed by 7 numbers.*

*If an accredited Third Party Review Organization (3P510k Review Organization) will be submitting this eSTAR, please enter “MD0000000” in this textbox.】*