**Application/Submission Type**

1 Application Jurisdiction

【Choose the jurisdiction you intend to submit to. If you change this option later to a new jurisdiction, data already entered that is applicable to the new jurisdiction will be conveyed over.】

【If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.】

【在填写eSTAR文档时，如果问题的附件都与该问题无关，或者对任何问题的回答不准确，则提交的材料可能会被提前暂停技术筛选，将要求纠正这些不足之处。

如，产品声明使用了“0”无线功能，但是设备实际使用了无线功能，错误地引用文本框中地附件或页码，在适用的文版框中声明“N/a”等；】

2 Application Purpose

【A Premarket Notification (510(k)) is a type of premarket submission that is intended to demonstrate that the device to be marketed is at least as safe and effective as a legally marketed device (21 CFR 807.92(a)(3)) that does not require PMA.

The De Novo process is a patheay to market by which devices not previously classifed, which are automatically classified in class III, can be placed into class II or I based on risk and based on the ability of general and special controls to reasonably assure safety and effectiveness.

Premarket Approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Please refer to the 21 CFR Part 814 and PMA site links for further information.】

3 Application Type

4 Application sub-Type

【“New Application/Submission” should be chosen if the application/submission is new.

When visible, the “Change to Application/Submission” option should be chosen if the submission is requesting a change to the content of an approved/authorized application, and the change requires a regulatory review according to the receiving jurisdiction.

“Additional Information” should be chosen when submitting additional information for an application/submission currently under review.

Once you receive an email that your eSTAR passed user fee validation, your original submission is grandfathered in to that eSTAR version. You should always use the eSTAR with your latest information when responding to an Additional Information request. For example, if you already modified your original eSTAR when responding to an Additional Information request and later you receive a second Additional Information request, you should modify the eSTAR you submitted in response to the first Additional Information request.】

【如果提交的申请需要更改已批准/授权的申请的内容(需要更改原提交的eSTAR)，则应该选择“Additional Information”；

在提交当前正在审查的申请/提交的附件信息时，也应该选择“Additional Information”；

在回复“Additional Information request”时，应该总是使用最新的eSTAR。例如，你已经修改了原始的eSTAR,之后你又收到了另外一个“Additional Information request”，你应该在上一个递交版本的eSTAR基础上更改，并递交最新的eSTAR。】