**Pre-submission correspondence**

*【递交前如与FDA有过沟通，或递交过，则需要按照以下描述准备相关资料。】*

*【Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information request.】*