**Minutes from Pre-Submission Meeting**

**Submission Number**: e.g., QYYNNNN or QYYNNNN/SNNN

**Submission Type**: e.g., Pre-Sub Meeting, Submission Issue Request

**Product Name**: Test ABC Device/Dx

**Sponsor/Submitter**: Company name

**Meeting Date/Time**: e.g., January 1, 2014; 2:00 pm

**Meeting Format**: Face-to-Face or Teleconference

**Date FDA Feedback was Sent**: e.g., December 25, 2013

**FDA Attendees**:

*(If you do not have this information, please contact your CDRH lead reviewer or CBER regulatory project manager via interactive review)*

Full Name Title; Organization

Full Name Title; Organization et cetera

**Sponsor Attendees**:

*(Please include titles and affiliation if more than one)*

**Discussion**:

*(Note: Please include a summary of key questions and decisions; this is not intended to be a transcript of the meeting, but should include any agreements reached and any items that require further consideration, as applicable. It is suitable to indicate, for example, “after some discussion, it was decided that the preclinical testing should address …”)*

*(Please refer to FDA or Sponsor name, as appropriate, rather than specific individuals.)*

*(If your presentation included any demonstrations, samples, models, et cetera, please do include a note to that effect.)*

*Sponsor X affirmed that it would be taking meeting minutes for this meeting.*

*Sponsor X presented its agenda for the meeting, including anticipated time allotted for each item.*

*Sponsor X briefly reviewed its purpose in submitting this Q-Sub and the current state of its device development.*

*Sponsor X indicated that, of the 5 questions it had posed in submitting this Q-Sub, it wanted to focus the meeting on questions 1, 3, and 5, since FDA’s responses to questions 2 and 4 appeared to be sufficient.*

*Sponsor X also wanted to clarify some of the additional feedback FDA had provided.*

*Question 1: (Your original question as submitted to FDA)*

*FDA Response to Question 1: (Optional) (Include the written response FDA provided prior to the meeting) (Minutes should capture if the company provided clarification or justification to anything in the original submission, if there was any clarification or justification to FDA’s written feedback, and if the company agreed or stated what its next steps would be. Do not capture the discussion verbatim. Clearly identify agreements and/or disagreements that were reached by FDA and the submitter during the discussion related to this specific question.)*

*Question 3:*

*…*

*Question 5:*

*…*

*Additional Feedback Item 1:*

*…*

**Decisions made and/or agreements reached**:

*KEY decisions or agreements should be listed succinctly here for easy reference later.*

*Reference the question # relevant to the decision or agreement that was reached during discussion of a specific question.*

**Action Items and Meeting Closure**:

*Sponsor X indicated that it had taken meeting minutes and would provide those to FDA within 15 days as an amendment to this Q-Sub.*

*(If Sponsor X indicated its next priority for a future FDA premarket submission, that would be useful to note)*

*(If either FDA or the company agreed to any action items post-meeting, beyond submitting the meeting minutes, those should be noted with a brief description, owner (FDA or Sponsor), and projected date for completion.)*

*Note:*

*If you presented slides at the meeting, you should include a copy of the slides with the meeting minutes.*