**References**

**1 Is literature referenced in the submission?**

【References may include legible copies, including translations where applicable, of manuscripts, journal articles, books, etc. This could also include a listing of published non-clinical studies involving the device(s)(e.g. cadaveric evaluations, biomechanical assessments). If clinical data were provided, clinical literature references should be included in the Clinical Testing section above.】

**2 Please add legible reprints or a summary of each article in English.**

【If your literature references can be viewed online, you may submit their web addresses in the attachment instead of legible reprints.】

**3 Please include a discussion of how each article is applicable to support the submission.**

【Your discussion could include the article title/citation, the purpose and stated hypotheses, methods used and stated acceptance criteria, results, and how the paper is being used to support the current submission (i.e., how the test article is representative of the subject device/product, a specific element of the study design, interpretation of the results as they apply).】