**Applicant Information**

*【Applicant: means any natural or legal person established within a country or jurisdiction who is legally responsible for the submission under that country or jurisdiction’s legislation. (IMDRF Common Data Elements Document)*

*(The term “person” that appears here includes legal entities such as a corporation, a partnership or an association.)*

*Correspondent: means the person designated by the owner or operator (i.e. Applicant) of an establishment as responsible for the receipt of pertinent correspondence from the FDA. (21 CFR 807.3)*

*The “Applicant” is also commonly referred to as the “Submitter” or previously “Sponsor” for 510(k)s, but is not necessarily the person who submits the 510(k). The “Applicant” is the proper term for PMAs, but is referred to as the “Requester” for De Novos. If the Correspondent is not the Applicant, please click the “Add Correspondent/Consultant” button below. 】*

1 Contact

2 Company

3 Pre-Submission Correspondence & Previous Regulator Interaction

3.1 Are there prior related submissions or regulator interaction for the subject device(s)?

*【During the product lifecycle, pre-submission correspondence, including teleconferences or meetings, may be held between the regulator and the applicant. Further, the specific subject device may have been subject to previous regulatory submissions to the regulator. The contents should be limited to the subject device as similar devices are addressed in other areas of the submission. If applicable, answer Yes.】*

3.2 Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

3.3 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 requests.

4 Standards

*【The Organization is the Standard Developing Organization (SDO) that developed the standard (e.g., UL, ISO). The Designation Number and Edition/Date identify the standard (e.g., 1642 5th Ed). The Title is the textual title (e.g., Lithium Batteries). The FDA uses recognition numbers for the standards they recognize (e.g., 19-10).*

*An international standard that another country adopts may be identical to standards recognized by FDA (e.g., ISO or IEC standards adopted as European Standards (EN/ISO), German standards (DIN/EN/ISO, DIN/ISO), or British standards (BS/ISO)). For example, if BS/EN/ISO 10993-5:2009 is used, you may use the same recognition number (2-245) as the parallel FDA recognized standard ISO 10993-5:2009. However, be sure to justify any country-specific differences in an attachment.】*

4.1 Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. A recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators request standards information be attached, see help text.

4.2 Are you using this standard for general use, or are you declaring conformity to it?

*【If you will declare conformity to the standard, a Declaration of Conformity (DoC) will be made for you near the end of this template, according to ISO 17050-1.*

*A DOC to a consensus standard may be used when a submitter certifies that its device conforms to all of the requirements of a consensus standard that FDA has recognized or decided to recognize. In a DOC, the submitter may not deviate from the consensus standard that FDA has recognized or decided to recognize.*

*General use of a consensus standard in premarket submissions refer to situations where a submitter chooses to conform to a consensus standard, in part or in whole, but does not submit a DOC. Also, a submitter may not submit a DOC if the submitter chose to rely on a consensus standard that FDA has not recognized or decided to recognize, or the submitter has deviated from an FDA-recognized consensus standard.*

*Under the ASCA (Accreditation Scheme for Conformity Assessment) Pilot, the FDA grants ASCA Recognition to qualified accreditation bodies to accredit testing laboratories to perform premarket testing for medical device companies. If you used an ASCA-accredited testing laboratory to conduct this testing, and an ASCA summary test report was provided, please indicate this.】*

4.3 Standards Details / Supplemental Documentation per ISO/IEC 17050-2

*【Supplemental information is typically needed if the standard doesn’t include both acceptance and test method(s) or procedure(s).*

*If you chose “Declaration of Conformity with ASCA,” please attach a declaration of conformity with the additional items recommended in the relevant standards-specific ASCA Pilot guidance document.】*