U.S. FOOD AND DRUG ADMINISTRATION
510(K) THIRD PARTY REVIEW PROGRAM SERVICES
SERVICE TERMS

These Service Terms shall govern United States Food and Drug Administration ("FDA") 510(k) Third Party Review Program Services performed by UL Contracting Party (as identified in the Quotation or Project Confirmation) and set out the responsibilities and obligations of the Client. These Service Terms and the terms of the Global Services Agreement ("GSA") are incorporated by reference into and are an integral part of each Service Agreement entered into by the Parties for U.S. Food and Drug Administration 510(k) Third Party Review Service. The capitalized terms in these Service Terms which are not defined herein shall have the same meaning as in the GSA.

1. **Scope of Service**. UL Contracting Party will review Client's 510(k) documentation in accordance with the FDA Accredited Person program. UL Contracting Party will then make a recommendation to the FDA Office of Device Evaluation ("ODE") regarding whether or not the device is substantially equivalent to a Predicate Device, as defined by the FDA and applicable laws and regulations. After the ODE reviews UL Contracting Party's recommendation and issues a decision, UL Contracting Party will forward to Client a letter transmitting the ODE's conclusions. The services requested by Client and to be provided by UL Contracting Party for specific projects shall be set out in individual Quotations or Project Confirmations.

2. **Price**. The Quotation or Project Confirmation will establish the price for Services. The price will depend upon the type of product and the test requirements. Any Quotation or Project Confirmation is subject to change at UL Contracting Party's discretion, upon reasonable notice to Client, and depending upon the requirements of the specific project.

3. **Client's Authorizations and Declarations**. Client warrants and represents that:

   (a) The work performed under this project will be made available to the FDA, upon its reasonable request, or if required by law.

   (b) Client has not submitted an application for the same device or for the same work submitted to UL Contracting Party to any other third-party organizations including, without limitation, the FDA.

   (c) Client authorizes UL Contracting Party to submit material on Client's behalf to the ODE.

   (d) Client agrees that UL Contracting Party is not required to give Client notice when any material associated with UL Contracting Party's files is made available to the FDA.

   (e) Client's Predicate Device is a "legally marketed predicate device," as defined by the FDA.

   (f) Client's Device is substantially equivalent to the Predicate Device.

4. **No Warranty of Acceptance by FDA**. UL Contracting Party does not guarantee or warrant that the FDA or any third party will accept its review or recommendation.

5. **Use of Names and Marks**. FDA 510(k) services shall not result in UL Contracting Party issuing product safety certification, or any authorization to use the Marks. Except as otherwise expressly authorized by UL Contracting Party, Client shall not use UL Contracting Party's, or any other UL Company's, name, abbreviation, symbols, Marks, or any other form of reference which may be interpreted to refer to UL Contracting Party or any other UL Company, on any goods or their containers or packaging, or in connection with any oral or written advertising, promotions, or otherwise.