



510k FDA Consulting

U.S. Agent Contract Denterprise International, Inc.

100 East Granada Blvd., Suite 219

Ormond Beach, FL 32176

386-506-8711

All foreign establishments must notify FDA of the name, address and phone number of their U.S. Agent. The U.S. Agent must either reside in the U.S. or maintain a place of business in the U.S. and must be available to answer the phone during normal U.S. business hours. The responsibilities of the U.S. agent are as follows:

1. Assisting FDA in communications with the foreign establishment;
2. Responding to questions concerning the foreign establishment's products that are sold in the United States;
3. Assisting FDA in scheduling inspections of the foreign establishment; and.
4. If FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, and such an action shall be equivalent to providing the same information or documents to the foreign establishment.

Our U.S. Agent Agreement includes only the above listed U.S. Agent responsibilities.

NOTE: Three (3) hours of regulatory support related to the responsibilities listed above are included with this agreement. Any additional support will be billed on an hourly basis.

Should you need additional services, we can provide regulatory, testing, preclinical, clinical, and compliance services to meet FDA requirements for 510(k), and IDEs. These services include, but are not limited to: FDA annual establishment registration and device listing, official correspondent responsibilities, resolution of import issues, regulatory strategy, required biological and/or functional testing, clinical study design and conduct, quality systems development and implementation, and writing regulatory submissions.

Please note that the U.S. agent has **no responsibility** related to reporting of adverse events under the Medical Device Reporting regulations, or submitting 510(k) Premarket Notifications. We provide those services in addition to our US Agent service.

NOTE: As your U.S. Agent the fee is \$1,500 annually. This agreement shall *automatically renew* and be extended from year to year upon the expiration of the Agency Term unless terminated by either party by written notice given to the other at least thirty days prior to its termination date.

Once this contract is signed and in place there will be no refund per this contract. If you wish to cancel Denterprise International, Inc. as your U. S. Agent, you may do so in writing, but nothing will be refunded.

If you are interested to use Denterprise International, Inc. as your U.S. Agent, please sign below for this service as a confirmation and return this to Lee@510kFDA.com. An invoice will follow.

Company: _____

Signature _____ Date _____