FDA MEDICAL DEVICE FACILITY REGISTRATION & LISTING
2020 RENEWAL QUESTIONNAIRE

1. **IF THERE HAS BEEN ANY CHANGES since this information was last reported to FDA, please provide the following information about the facility:**

   ☐ **NO CHANGES**

   ☐ **YES, PLEASE MAKE THE FOLLOWING CHANGES TO OUR REGISTRATION AND/OR LISTING:**

   a. Name: _____

   b. Address: _____

   c. Telephone:_____ Fax:_____

   d. URL: _____

   e. Other business trade names: _____

   f. Contact Person: _____

   g. Title: _____

   h. E-mail address: _____

2. **Please list every *new* medical device manufactured, assembled, or imported by this facility, to be sold in the U.S., which HAS NOT YET BEEN REPORTED TO THE FDA:** *If you need additional space , please write on back or on separate sheet of paper*

Proprietary Device Name	Device description and Intended Use	Manufacturer Name, Address and FDA Registration No.	Name, Address and FDA Registration No. for All known U.S. importers of device	FDA Class (if known) Class I or Class II

CONTINUED ON NEXT PAGE

3. Select all activities related to the device(s) listed with the FDA that are performed at the facility listed above:

- ☐ **Contract Manufacturer** - Manufactures a finished device to another establishment's specifications.
- ☐ **Contract Sterilizer** - Provides a sterilization service for another establishment's devices.
- ☐ **Foreign Exporter** - Exports or offers for export to the United States (U.S.), a device manufactured, prepared, propagated, compounded, or processed in a foreign country, including devices originally manufactured in the United States. A foreign exporter must have an establishment address outside the U.S.
- ☐ **Initial Importer** - Takes first title to devices imported into the U.S. An Initial Importer must have a U.S. address.
- ☐ **Manufacturer** - Makes by chemical, physical, biological, or other procedures, any article, accessory, component, or kit that is packaged or labeled for commercial distribution for health-related purposes. This definition excludes manufacturers of components that are distributed only to a finished device manufacturer.
- ☐ **Repackager** - Packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding shipping containers).
- ☐ **Relabeler** - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.
- ☐ **Remanufacturer** - Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.
- ☐ **Reprocessor of Single Use Device** - Performs remanufacturing operations on a single use device.
- ☐ **Specification Developer** - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing. This includes establishments that, in addition to developing specifications, also arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.
- ☐ **U. S. manufacturer of export only devices** - Manufactures medical devices that are not sold in the U.S. and are manufactured solely for export to foreign countries.
- ☐ **Complaint file establishment** per 21 CFR §820.198.

*****The FDA requires payment of FDA Annual Registration Fee prior to renewal of a facility registration. The FDA Annual Registration Fee for 2019 is $4,884. *****

CONTINUED ON NEXT PAGE

ACKNOWLEDGMENT OF DESIRE TO EMPLOY FIRM

I am retaining Ann Marie Gaitan, Esq. to process a medical device facility renewal for calendar year 2019, for the above-named medical device facility, for which I am an authorized agent. I would like the firm to provide the following services (*please select all that apply*):

- ☐ **Domestic Firm Registration Renewal**: $5,359 USD ($475 USD for legal fees + $4,884 USD for FDA Registration Fee).
- ☐ **International Firm Registration Renewal:** $5,509 USD ($625 USD for legal fees and U.S. Agent services for 2019 + $4,884 USD for FDA Registration Fee).
- ☐ **Additional Medical Device Listing:** $100 per device

By completing this form and signing below, I am confirming my desire to engage this law firm to provide the above-selected services and agree to remit the necessary fees for the provision of same.

Signed:_____ Printed Name:_____ Date:_____

For Payment of legal fees, please follow below instructions:

VIA RA GAITAN LAW QUICKBOOKS INVOICE (FREE):	**VIA WIRE TRANSFER*:**
Please follow the instructions provided on the electronic invoice. You can begin payment process by pressing "Pay now" on invoice. Please have checking account information on hand to complete the transaction.	Please send transfer to: Please contact our firm for wire instructions ***Client is responsible for all transfer fees.*** *Please check with bank and include transfer fees with payment. Renewals will not be processed until legal fees are paid in full.*

Completed forms may be sent via e-mail to rg@ragaitanlaw.com

Please return the completed form, along with payment to our office ***before December 20, 2019*** to allow for timely processing.

FDA REGISTRATION RENEWAL FEE CREDIT CARD AUTHORIZATION

Please provide credit card information below authorizing our Firm to process payment for the FDA fees of $4,884 directly to the FDA.

Please note that you will not be invoiced by our Firm for these fees, rather you will receive an e-mail confirmation from the FDA and a charge from the U.S. Government on your credit card invoice.

Account Holder Name:	
Payment Amount:	
Billing Address:	
Billing Address 2:	
City:	
State / Province:	
Zip / Postal Code:	
Country:	
Card Type: *** Visa, MasterCard, AMEX, or Discover**	
Card Number:	
Security Code:	
Expiration Date:	

Authorized by: _____

Signature: _____

Date: _____