

**AGREEMENT FOR SERVICES AS
UNITED STATES AGENT**

Pursuant to 21 CFR 807.40

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THIS AGREEMENT is entered into by and between USDeviceAgent.com, (hereinafter AGENT), and _____, (hereinafter COMPANY), of

_____ Country _____

WHEREAS AGENT offers regulatory services to medical device companies pursuant to the United States Food and Drug Administration regulations found at 21 CFR 807.40, (hereinafter the Regulation), requiring appointment of a resident U.S. agent effective February 11, 2002; and,

WHEREAS Company wishes to engage the professional services of Agent in compliance with the above said regulation;

NOW THEREFORE, for the mutual promises, covenants, and other good and valuable consideration further described hereinafter, the parties agree as follows:

1. TERM:

A. This Agreement is effective on the _____ day of _____, 2002, (the Effective Date), and is for a period of One (1), Two (2) or Three (3) years as indicated by the selection made in Section 1(D) below. Termination of the Agreement shall occur on the first, second, or third anniversary commensurate with said selection.

B. The One Year version of this Agreement shall automatically renew, unless Company notifies Agent in writing at least sixty (60) days prior to the anniversary of the then current contract. Any renewal hereof shall be at the then current Engagement Fee

C. In the event Agent does not intend to renew this Agreement Agent must so notify Company of this intent within thirty (30) days of the termination of the then current contract.

D. The term of this Agreement is for one of three periods as follows and company selects the period of its choice by its authorized signature in the place provided:

One Year	Selected _____ Company
Two Year	Selected _____ Company
Three Year	Selected _____ Company

2. ENGAGEMENT FEE:

A. Company shall pay Agent a fee to act as its U.S. agent for a period of time as provided below in accordance with the selection made in Section 1(D) above, starting on the Effective Date. Fees paid under this Agreement shall be deemed a fully earned retainer, in consideration for committing availability, and not subject to refund except as provided hereinafter in section 9.

1) U.S. Agent for Devices – 1 Year retainer \$1,500

2) U.S. Agent for Devices – 2 Year retainer \$2,500

3) U.S. Agent for Devices – 3 Year retainer \$3,000

B. Payment of the Fee, in US currency, shall be made upon signing of this Agreement by electronic transfer to Agent's bank pursuant to transfer instructions provide by Agent at the execution of the Agreement, by credit card payments accepted through the Agent's website (www.USDeviceAgent.com) or by Company check. Any delay in receipt of funds will delay the Effective Date of this Agreement by the delay period.

3. DUTIES OF AGENT:

A. Agent shall:

1. Maintain a place of business including a telephone, email and fax connection within the United States of America during the Term of this Agreement or any renewals thereof.
2. Assist Company in filing FDA Form 2891 with FDA, which meets the FDA requirement for registration and identifies Agent as the United States Agent for the Company.
3. Accept all calls from the FDA regarding the Company or its products and report to Company, within TWO (2) business days, Saturday, Sunday and U.S. recognized holidays excluded, a summary of said calls.
4. Assist FDA, as contemplated by the Regulation, in communications with the Company.
5. Respond to questions, either by direct response or by a commitment to FDA to provide a timely response following consultation with the Company, regarding products that are imported or offered for import into the United States.
6. Provide liaison between FDA and the Company in scheduling inspection(s) of the facilities of the company.

B. Absent a separate agreement to the contrary, Agent shall NOT:

1. Provide any legal advice on any matters of conflict with FDA or advise Company on issues of compliance with Quality System Regulations as described at 21 CFR 820.
2. Provide any services relative to the administration of FDA required reports under the Medical Device Reporting regulation found at 21 CFR 803 except as necessary to facilitate communications between the FDA and Company as contemplated by the Regulation.
3. Provide assistance in any way regarding the preparation or filing of any documents with FDA regarding premarket approvals or supplements, premarket notifications, investigational device exemptions.

4. DUTIES OF COMPANY:

A. Company shall, upon execution of this Agreement provide Agent with:

1. A list of contacts at Company, in descending order of priority, including their telephone, email and fax numbers. The list shall include at least one (1) 24 hr contact by name, title and telephone number for emergency contact purposes. This list shall be maintained current at all times and Company shall update it as appropriate within two (2) days of any changes.

2. A complete and current catalog of all products imported into, or offered for sale in, the U.S.. This list will be kept current and Agent will be advised of any changes thereto in a timely manner.
3. A current list of all PMA's, 510(k)s, or IDE's and listing of all said products. This will be updated in a timely manner as additions or deletions are made.
4. A response, within three (3) business days, to all inquiries from FDA passed on to Company by Agent pursuant to the terms of this Agreement.

5. CONFIDENTIALITY:

Agent shall maintain confidentiality with regards to its actions pursuant to this Agreement and shall not disclose the content or substance of any FDA contacts to anyone other than the individuals identified in Section 4(A)(1) above, unless otherwise authorized in writing by the Company. All documents, records, information and the like that Company considers to be its confidential information shall be so identified on its face and Agent shall maintain confidentiality of said confidential information with the same care Agent treats Agent's own confidential information.

The above notwithstanding, the obligation to maintain confidentiality shall not apply to information:

That was known to the public at the time Agent received it;

That was disclosed to the public after Agent received it through no fault of the Agent;

That was disclosed to Agent by a third party;

Disclosure of which is required under law or regulation

6. INDEMNITY:

Company acknowledges that the duties of Agent under this Agreement are limited to those contemplated by FDA in the regulation and that Agent is not in any way involved in the design, development, promotion, marketing, sale, manufacture or quality inspection of any of the products imported, or offered for import, into the U.S.. Company shall defend, indemnify and hold Agent, his officers, agents, consultants, directors, employees and/or his associates harmless from all claims for any reason whatsoever from any third party against the Company or any of its products.

7. INSURANCE:

Company represents that it has a current General Corporate Liability policy effective in the U.S. with a limit of at least \$5,000,000 per occurrence in full force and effect within the U.S. and Company Agrees to name Agent as an also insured under that policy for the term of this Agreement or any renewals thereof. Company shall provide documentary evidence of this coverage within two (2) weeks of entering this Agreement. Failure to do shall constitute a material breach of this Agreement.

8. INDEPENDENT AGENT:

Agent is an independent agent and is not authorized to, nor obligated to, obligate the Company in any matter whatsoever.

9. TERMINATION:

A. Without Cause:

This Agreement may be terminated without cause by either party upon thirty (30) days prior written notice of the intent to do so. If the Company terminates this Agreement under this section it will not be entitled to a refund of fees paid. If Agent terminates this Agreement, Agent will refund a prorated portion of the Fees.

10. GOVERNING LAW

This Agreement is deemed to be executed at Riverside, Riverside County, California, and shall be governed according to the laws of California by the Superior Court of California in Riverside County

11. COUNTERPARTS:

This Agreement is executed in two counterparts, either of which is deemed an original.

12. TOTAL AGREEMENT:

This Agreement constitutes the total agreement between the parties and all prior discussions are incorporated hereinto. No change shall have any force or effect on this Agreement unless it be reduced to writing and signed by both parties.

UNDERSTOOD AND AGREED TO:

AGENT:

COMPANY:

Authorized signature:

USDeviceAgent.com

By:_____

Print Name:_____

Title:_____

Date:_____

Date:_____