APPOINTMENT OF U.S. AGENT AGREEMENT

[redacted] Ltd
Address: [redacted]
Contact: [redacted]
Tel: [redacted]
E-mail: [redacted]
(hereinafter referred to as Company A)

and
Simply Shipped, LLC
12745 W Townsend StBrookfield, WI 53005USA
Contact: Mike Ryan
Tel: +001-414-326-4114
E-mail: simplyshipped.agent@gmail.com
Fax: +001-866 615-2434
(hereinafter referred to as Company B)

WHEREAS Company B 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 ; and, WHEREAS Company A wishes to engage the professional services of Company B 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 signature date of Company A and Company B,and is for a period of (3) years as indicated by the selection made in Section 1(D) below.

B. This Agreement shall automatically renew at end of 3years unless Company A notifies Company B in writing at least thirty (30) 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 Company Bdoes not intend to renew this Agreement Company Bmust so notify Company A of this intent within thirty (30) days of the termination of the then current contract.

D. The term of this Agreement is for (3) years US Agent Service authorized by Company A.

2. DUTIES OF Company B:

2.1 Company B shall:

2.1.1 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.

2.1.2 Assist Company A in filing FDA registration data, which meets the FDA requirement for registration and identifies Company B as the United States Agent for the Company A.

2.1.3 Accept all calls from the FDA regarding the Company A or its products and report to Company A, within five (5) business days, Saturday, Sunday and U.S. recognized holidays excluded, a summary of said calls.

2.1.4 Assist FDA, as contemplated by the Regulation, in communications with the Company A.

2.1.5 Respond to questions, either by direct response or by a commitment to FDA to provide a timely response following consultation with the Company A, regarding products that are imported or offered for import into the United States.

2.1.6 Provide liaison between FDA and the Company A in scheduling inspection(s) of the facilities of the company A.

2.2 Absent a separate agreement to the contrary, Company B shall NOT:

2.2.1 Provide any legal advice on any matters of conflict with FDA or advise Company A on issues of compliance with Quality System Regulations as described at 21 CFR 820.

2.2.2 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 A as contemplated by the Regulation.

3. DUTIES OF COMPANY A:

3.1 Company A shall, upon execution of this Agreement provide Company **B** with:

3.1.1 A list of contacts at Company A, in descending order of priority, including their telephone, email and fax numbers. The list shall include at least one (1) 24-hour contact by name, title and telephone number for emergency contact purposes. This list shall be maintained current at all times and Company A shall update it as appropriate within five (5) days of any changes.

3.1.2 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 Company B will be advised of any changes thereto in a timely manner

3.1.3 A current list of all PMA's, 510(k)s, or IDEs and listing of all said products. This will be updated in a timely manner as additions or deletions are made.

3.1.4 A response, within five (5) business days, to all inquiries from FDA passed on to Company A by Company B pursuant to the terms of this Agreement.

4. CONFIDENTIALITY:

Company B 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 3.1.1 above, unless otherwise authorized in writing by the Company A.All documents, records, information and the like that Company A considers to be its confidential information shall be so identified on its face and Company B shall maintain confidentiality of said confidential information with the same care Company B treats Company B'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 Company B received it;

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

That was disclosed to Company B by a third party;

Disclosure of which is required under law or regulation

5. INDEMNITY

Company A acknowledges that the duties of Company B under this Agreement are limited to those contemplated by FDA in the regulation and that Company B 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 A shall defend, indemnify and hold Company B, 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 A or any of its products.

6. INDEPENDENT Company B:

Company B is an independent agent and is not neither authorized to, nor obligated to, obligate the Company A in any matter whatsoever.

7. TERMINATION:

This Agreement may be immediately canceled upon the occurrence of one of the

following:
a) The failure of one party to perform or comply with any one or more of the terms and/or conditions set forth in this agreement.
b) The discontinuance for any reason whatever of the performance of either party's specified duties for a period of thirty (30) days; and/or
c) The insolvency of either party or the filing of a bankruptcy petition against it.

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

9.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.

10. The products covered by this agreement:

Device/Model(s): [redacted]
Product Code: ISA

Device/Model(s): [redacted]
Product Code: KNM

UNDERSTOOD AND AGREED TO:

Company A: _____ _____
Date Signature

Company B: _____ _____
Date Signature