

Local Representative Letter
For Certification Service in the USA

Federal Communications Commission
Equipment Authorization Division, Application Processing Branch
7435 Oakland Mills Road
Columbia, MD 21048

To whom it may concern

Pursuant to Section 2.911(d)(7), of the Commission's Rules (47 C.F.R.) we attest as follows for the product listed below:

FCC ID	Model name
2BQKL-HB-13	HB-13

We hereby acknowledge as follows:

- i. both signees confirm that the point of contact accepts responsibility to act as a US-American Representative on behalf of the applicant
- ii. the point of contact provides the physical U.S. address and email as listed below
- iii. both parties maintain the requirements of this agreement for no less than one year after the grantee has terminated all marketing and importation or the conclusion of any Commission-related proceeding involving the equipment.
- iv. An expiration date for this letter does not exist. In case the U.S. agent changes, the grantee is obligated to notify the FCC within 30 days via the granting TCB.

US-American Point of Contact

Applicant/Approval Holder

Cindy Wu

Liao Jinli

Signature Date: 2025-7-9

Signature Date: 2025-7-9

Company Name: HOORAY INDUSTRY LLC

Shenzhen Binxinyan Electronics
Co., Ltd

FRN: 0033926106

0037214905

Contact Name: Cindy Wu

Liao Jinli

Address: 1408 Pinon Place Fullerton, CA
92835 United States

7E Lixuan Pavilion, Pengli
Building, No. 1039 Huaqiang
South Road, Chiwei
Community, Nanyuan
Street, Futian
District, Shenzhen, China
18589044591

Phone: (626) 910-5808

Email: cindynewhope@gmail.com

724318155@qq.com

2018-07-10 10:00:00 - 2018-07-10 10:00:00

1. **What is the main purpose of the study?**
The main purpose of this study is to evaluate the effectiveness of the new treatment (the combination of the traditional Chinese medicine and the Western medicine) in the treatment of the patients with the primary progressive multiple sclerosis (PPMS).
2. **What is the study design?**
The study is a double-blind, randomized, controlled trial.
3. **Who is eligible to participate in the study?**
The study is open to the patients with the primary progressive multiple sclerosis (PPMS) who are 18 years old or older and have been diagnosed with the disease for at least 2 years. The patients should be able to understand the study and provide informed consent. The patients should be able to follow the study protocol and take the study drugs as prescribed. The patients should not be pregnant or lactating. The patients should not be taking any other medications that may interfere with the study drugs. The patients should not have any other medical conditions that may interfere with the study.
4. **What are the inclusion criteria?**
The inclusion criteria are:
- Age: 18 years old or older.
- Diagnosis: Primary progressive multiple sclerosis (PPMS).
- Duration: At least 2 years.
- Ability to understand the study and provide informed consent.
- Ability to follow the study protocol and take the study drugs as prescribed.
- Not pregnant or lactating.
- No other medical conditions that may interfere with the study.
5. **What are the exclusion criteria?**
The exclusion criteria are:
- Age: Less than 18 years old.
- Diagnosis: Secondary progressive multiple sclerosis (SPMS).
- Duration: Less than 2 years.
- Not able to understand the study and provide informed consent.
- Not able to follow the study protocol and take the study drugs as prescribed.
- Pregnant or lactating.
- Other medical conditions that may interfere with the study.

6. **What are the study drugs?**
The study drugs are:
- Traditional Chinese medicine (TCM): A combination of several traditional Chinese herbs that have been used for centuries to treat various diseases. The specific combination of herbs will be determined by the study physician based on the patient's individual needs.
- Western medicine: A combination of several Western drugs that have been developed for the treatment of multiple sclerosis. The specific combination of drugs will be determined by the study physician based on the patient's individual needs.
7. **What are the study procedures?**
The study procedures are:
- Baseline evaluation: A series of tests and evaluations to determine the patient's baseline status. This includes a physical examination, laboratory tests, and imaging studies.
- Randomization: The patient will be randomly assigned to one of two treatment groups: the TCM group or the Western medicine group.
- Treatment: The patient will receive the assigned treatment for a specified period of time. The treatment will be provided by a study physician.
- Follow-up: The patient will be followed up at regular intervals to monitor the progress of the disease and the effectiveness of the treatment. The follow-up will include physical examinations, laboratory tests, and imaging studies.
8. **What are the study outcomes?**
The study outcomes are:
- Primary outcome: The primary outcome is the progression of the disease, as measured by the Expanded Disability Status Scale (EDSS). The EDSS is a scale that measures the level of disability in patients with multiple sclerosis, ranging from 0 (no disability) to 10 (severe disability).
- Secondary outcomes: Secondary outcomes include the following:
- Quality of life: The patient's quality of life will be assessed using the Multiple Sclerosis Quality of Life Inventory (MSQOL-54).
- Cognitive function: The patient's cognitive function will be assessed using the Mini-Mental State Examination (MMSE).
- Functional status: The patient's functional status will be assessed using the Functional Independence Measure (FIM).
- Adverse events: The patient's adverse events will be monitored and recorded.

9. **What are the study results?**
The study results are:
- Primary outcome: The results show that the combination of TCM and Western medicine is effective in slowing down the progression of the disease. The patients in the TCM group had a lower EDSS score compared to the patients in the Western medicine group at the end of the study.
- Secondary outcomes: The results show that the combination of TCM and Western medicine is effective in improving the patient's quality of life, cognitive function, and functional status. The patients in the TCM group had better scores on the MSQOL-54, MMSE, and FIM compared to the patients in the Western medicine group.
- Adverse events: The results show that the combination of TCM and Western medicine is well-tolerated and safe. There were no serious adverse events reported in either group.
10. **What are the study conclusions?**
The study conclusions are:
- The combination of TCM and Western medicine is effective in the treatment of primary progressive multiple sclerosis (PPMS).
- The combination of TCM and Western medicine is well-tolerated and safe.
- The combination of TCM and Western medicine is a promising new treatment for PPMS.
- Further research is needed to confirm these findings and to determine the optimal combination of TCM and Western medicine for the treatment of PPMS.