Shanghai Municipal Drug Administration

Application for change of Type II medical device permit

This application form should be filled in completely. If there is no relevant information, please fill in the "/".

Product name		Ear Back Hearing Aid		
Name of registration applicant		Hearing Aid (Shanghai) Co., Ltd		
Application type		change of Type II medical device		
Original registration number		Shanghai Machinery Registration 20172460454		
Registered contact person	Full name	Gao Meijuan	Tel	13916831048
	Fax	021-63265101	Mobile phone	15821941102
	Address	10/f, no. 126, Jiangchang 3rd road, Jing An district, Shanghai		
	Postal Code	200436	E-mail	widex@widex.com.cn
Unified social credit code		913100006073960219		
Legal representative or person in charge of the enterprise		Gu Yuqing	Telephone number of legal representative or person in charge of enterprise	021-66775837-118
Agent		Gao Meijuan	Telephone number of agent	13916831048
Change matters		Product technical requirements; product scope of application; specifications, models		
Change content		Add the product type: Before change: see the Appendix 1 “after the change of the product type and specification” for details. After change: see the Appendix 1 “after the change of the product type and specification” for details. Add the scope of application: Before change: Provide hearing compensation for hearing loss patients After change: Provide hearing compensation for hearing loss patients. At the same time, it can produce fractal tones to help subjective tinnitus patients with symptoms		

Other issues that need to be addressed	In the original application, the product's Zen sound was used as an additional feature for users to choose from, and Zen sound is a tool for tinnitus treatment. In this application, Zen as a tool for tinnitus treatment was declared as the expected range of adaptation. The Zen sound function in this product should be checked by a designated professional hearing clinic or a testing facility, and the function parameters should be set by a professional hearing health care specialist (audiologist, hearing aid specialist, Otolaryngology) trained in hearing rehabilitation. At the same time, the optometrist should keep the patient's medical records. Tinnitus patients should be in accordance with the requirements of professional hearing health experts, regular use of follow-up (follow-up period ranging from 1 to 6 months), in each follow-up to provide and maintain a complete record of the case (test debugging records) .

The applicant is aware that State Council of the People's Republic of China Order No. 680

The Medical Device Regulatory Ordinance, provides that:

Article 64 Providing false information or using other fraudulent means to obtain medical device registration certificate, medical device production license, medical device business license, large-scale medical device configuration license, advertising approval document and other license documents. The Original License Issuing Department shall revoke the obtained license and impose a fine of not less than 50,000 yuan and not more than 100,000 yuan. Within 5 years, the application for medical device license submitted by the responsible person or unit shall not be accepted.

Article 65 Those who fail to put on record in accordance with these regulations shall be ordered to make corrections within a time limit by the Government of the People's Republic of China at or above the county level. Those who do not make corrections within the time limit shall announce to the public the names of units and products that have not been put on record, and may be fined not more than 10,000 yuan.

If false information is provided during the filing, the Government of the People's Republic of China at or above the county level shall announce the filing unit and the name of the product to the public. If the circumstances are serious, the persons directly responsible shall not engage in the production and operation of medical devices within 5 years.

Applicant (signature and seal)

Date: mm / DD / yyyy