

Fiscal Year 2024

FDA Registration Confirmation

Manufacturer: **XIAMEN YIZHOU IMP. & EXP. CO., LTD.**

Address: **201,2F,Huili Industrial Park,Meixi Rd.,TongAn District,, Xiamen, Fujian, 361100, CHINA**

US Agent: Regrek LLC

Address: 19 Holly Cove Ln.,Dover, Delaware, 19901, UNITED STATES

The facility registration and device listing information:

Registration Number:3008763803 Owner/Operator Number: 10053196

Device Listing#: See annex

This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration.

Signature: Elaine Huang

Date: Dec. 12, 2023

Place: China/ Fujian

Expiration Date: Dec. 31. 2024



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ANNEX:

Listing No	Code	Device Name	Proprietary Name
D278965	LWF	DILATOR, NASAL	Nasal Dilator
D278966	EHY	TRAY, IMPRESSION, PREFORMED	Anti Snore Mouth Tray; Mouthguard; Impression Mouth Tray(For grinding,TeethWhitening)
D278967	IQF	ORTHOSIS, CERVICAL-THORACIC, RIGID	plastic case
D278969	EIG	RETRACTOR, ALL TYPES	Cheek Retractor
D328001	EEG	HEAT SOURCE FOR BLEACHING TEETH	teeth whitening LED light;teeth whitening light; teeth whitening mouth tray LED light;teeth whitening accelerator
D342324	OBR	MOUTHGUARD, OVER-THE-COUNTER	Bright Guard
D415668	BRW	PROTECTOR, DENTAL	GuardianZPro
D426244	LRJ	DISINFECTANT, MEDICAL DEVICES	Eliminator Box
D432553	LQZ	DEVICE, JAW REPOSITIONING	/
D432553	LRK	DEVICE, ANTI-SNORING	/

END OF THE ANNEX

Signature: Elaine Huang

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