

FDA

Fiscal Year 2025

This is a notice to the establishment whose Facility Registration and Device Listing have been done within the Fiscal Year 2025.

Establishment information

Name: JIANGXI IVISMILE TECHNOLOGY CO.,LTD

Address: No. 878 Xinwang Road, Traditional Chinese Medicine Industrial Park, Zhangshu City, Yichun City, Jiangxi, 331200, CHINA

Inquiry Website: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

Facility Registration and Device Listing Information

Owner/Operator Number: 10091608

Registration Number:

You will receive another e-mail providing you with your registration number **in approximately 30 to 90 days**. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Listing No.	Product Code	Proper Name(s)	Registration Role
D546267	KHA	face mask, disposable face mask, mouth mask, sanitary Mask	Manufacturer
D546270	MAU	Aroamas Teeth Whitening Pen 3 Pack; Aroamas TEETH WHITENING KIT; AsaVea Teeth Whitening Pen (2 Pack); AsaVea Premium Teeth Whitening Kit, LED Light; Dry Strips; Dissolving Strip; Teeth Whitening Pen; Bleaching Pen; BANANA WHITE Teeth Whitening Gel; BANANA WHITE Teeth Whitening Kit; Coconut Oil Sachet; Remineralization Gel; Desensitizing Gel; Teeth Whitening Kit; Teeth Whitening Home Kit; Desensitizing Serum; Teeth Bleaching Kit; Teeth Whitening Strips; Double Elastic Gel Strips; ECLA Teeth Whitening Strips; ECLA Teeth Whitening Gel; ECLA Purple Corrector; OLLM Teeth Whitening Kit; IBTISAMATI Teeth Whitening Kit; IVISMILE teeth whitening foam; IVISMILE charcoal powder; IVISMILE teeth whitening powder; ivismile teeth whitening kit, gemzeez teeth whitening strips; IVISMILE teeth whitening kit; IVISMILE teeth whitening gel; IVISMILE teeth whitening pen; IVISMILE teeth whitening strips; IVISMILE	

		teeth whitening light; IVISMILE whitening foam; Just Smile Teeth Whitening Kit, Smilewhite Teeth Whitening Kit; Max whitening gel; REAL WHITE Teeth Whitening Kit; REAL WHITE Teeth Whitening Gel; Primal Life Teeth Whitening Kit; Maximum Strength Serum; Teeth Whitening Wands; MONASMILE Teeth Whitening Kit YF-TWK-003; Smilex teeth whitening kit; CLARTE Teeth Whitening Kit; Premium Teeth Whitening System - LED Light; Teeth Whitening System; Teeth Bleaching System; Primal Life teeth whitening gel; BOKA teeth whitening kit; BOKA teeth whitening Gel; BOKA teeth whitening strips; Professional Whitening Gel; Dual Barrel Gel; Double Barrel Gel; Teeth Whitening Pen [3 Pens]; Purple Teeth Whitening Strips; Purple Teeth Whitening Foam; ECLA Teeth Whitening Kit; Teeth Whitener; Dual Barrel Syringe Gel; Double Barrel Syringe Gel; Teeth Whitening Powder; Coconut Oil Pulling; Teeth Whitening Foam; Charcoal Teeth Whitening Strips; Teeth Whitening Gel 2ml/3ml/4ml/5ml/10ml; Tetyana Naturals Teeth Whitening Pen (2 Pack), Max gel, LAB Teeth Whitening Gel	
D546272	KXF	Vitamin E Swab	
D546274	EEG	Mini Light 1led/5led;Teeth Whitening Light 8led/16led/32led;Teeth Whitening Led Light 8led/16led/32led; Plusma Light; Moons, Moonlight; Pola LED mouthpiece; ProLite LED Teeth Whitening Device; Smart Teeth Whitening Light; Teeth Whitening Lamp; Teeth Whitening Accelerator; Teeth Whitening Mini Light; Teeth Whitening Light; Teeth Whitening Led Light; Portable Teeth Whitening Light; Smart Teeth Whitening Device; Teeth Whitening Mouth Tray Led Light; Teeth Whitening Mouth Tray Light; Wireless Mouthpiece Led Light, Wireless Teeth Whitening Device	
D546275	LWF	Stop Snoring Chin Strap; Anti Snore Jaw Supporter; Stop Snoring Solution; Anti Snore Belt; Chin Strap Belt	
D546276	EHY	Foam Strip Mouth Tray; Gel Prefilled Mouth Tray; Thermoplastic Mouth Tray; Mouth Piece; Teeth Whitening Mouth Tray	
D546277	EIG	Cheek Retractor; Mouth Opener; Lip Retractor	
D546278	EFT	Denture Cleansing Tablet	
D546279	JEQ	2pack toothbrush head; toothbrush head refills; toothbrush heads; Max whitening gel; Electric Toothbrush; Sonic Toothbrush; Electric Led Toothbrush; Sonic Led Toothbrush; IVISMILE electric toothbrush; replacement toothbrush head; toothbrush head; refill toothbrush head; single refill toothbrush head;	

D546280	EIE	Dental Dam; Dental Gum Dam; Gum Protector Gel; Gingival Protection Gel
D546281	BYP	Anti Snore Kit; Stop Snoring Device; Anti Snore Mouth Piece; Snoring Stopper; Anti Snore Mouth Tray; Stop Snoring Solution
D546282	EFW	Finger Brush; Oral Brush Ups; Teeth Wipes; Brush Ups; Toothbrush, Bamboo Toothbrush
D546284	LYU	Isolation mask
D546285	JES	Dental floss
D546286	EMN	Dental Teeth Cleaner
D546287	EFS	Water flosser