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Annual Registration Successful

Facility: XIAMEN HUAKANG ORTHOPEDIC CO.,LTD, Xiamen City, Fujian, CHINA

You have successfully updated your registration and listing information for 2026.

Your registration will be valid through Dec 31, 2026.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2026.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10055922.

Facility Information

Registration Number:
3008903689

Initial Importer:
N

Facility Name:
XIAMEN HUAKANG ORTHOPEDIC CO.,LTD

Legal Name:

Address:
2F,Building #13, No. 2881 Dongfu Avenue, Haicang District,
Xiamen City, Fujian, 361027, CHINA

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
10055922

Contact Name:
Yong Xiao

Company:
XIAMEN HUAKANG ORTHOPEDIC CO.,LTD

Address: 2F,Building #13, No. 2881 Dongfu Avenue, Haicang District
Xiamen City, FUJIAN, 361027, CHINA

Telephone:
86 - 592 - 6083387

Fax:
-

E-mail: inquirymed@hotmail.com

DUNS Number:

Official Correspondent Information

Contact Name:
Yong Xiao

Company:
XIAMEN HUAKANG ORTHOPEDIC CO.,LTD

Address: 2F,Building #13, No. 2881 Dongfu Avenue, Haicang District
Xiamen City, FUJIAN, 361027, CHINA

Telephone:
86 - 592 - 6083387

Fax:
-

E-mail: inquirymed@hotmail.com

DUNS Number:

United States Agent Information

Contact First Name
Leeyeo

Contact Last Name
Kee

Contact Title:
Mr

Business Name:
Regrek LLC

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

Phone:
302 - 6089028

Fax:

DUNS Number:

E-mail: regrek.cs@hotmail.com

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Importers
D374922		510(k) exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer Foreign Exporter	
D381357		510(k) exempt	OEA	Non-surgical gown	Foreign Exporter Manufacturer	
D488401		510(k) exempt	EXN	SUPPORT, HERNIA	Manufacturer Foreign Exporter	
D304744		510(k) exempt	ITW	JOINT, ANKLE, EXTERNAL BRACE	Manufacturer Foreign Exporter	
D333984		510(k) exempt	IPR	CRUTCH	Manufacturer Foreign Exporter	

D304743		510(k) exempt	ITQ	JOINT, KNEE, EXTERNAL BRACE	Foreign Exporter Manufacturer	
D304742		510(k) exempt	IQK	Orthosis, cervical	Manufacturer Foreign Exporter	
D304741		510(k) exempt	ISR	BAND OR BELT, PELVIC SUPPORT	Manufacturer Foreign Exporter	
D333985		510(k) exempt	IQI	ORTHOSIS, LIMB BRACE	Manufacturer Foreign Exporter	
D304746		510(k) exempt	ILG	STOCKING, ELASTIC	Manufacturer Foreign Exporter	
D304745		510(k) exempt	FSD	BINDER, ABDOMINAL	Manufacturer Foreign Exporter	
D556004		510(k) exempt	MRI	ORTHOSIS, TRUNCAL/ORTHOSIS, LIMB	Foreign Exporter Manufacturer	
D381356		510(k) exempt	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratic eyewear)	Manufacturer Foreign Exporter	
D479790		510(k) exempt	CCX	SUPPORT, PATIENT POSITION	Foreign Exporter Manufacturer	
D304656		510(k) exempt	IQJ	SPLINT, CLAVICLE	Manufacturer Foreign Exporter	
D304657		510(k) exempt	ILI	SLING, ARM	Foreign Exporter Manufacturer	

Date of Initial Registration: 2017-10-18 06:56:54.0

FDA

Fiscal Year 2026

This is a notice to the establishment whose Facility Registration and Device Listing have been done within the Fiscal Year 2026.

Establishment information

Name: XIAMEN HUAKANG ORTHOPEDIC CO.,LTD

Address: 2F,Building #13, No. 2881 Dongfu Avenue, Haicang District, Xiamen City, Fujian, 361027, CHINA

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

Facility Registration and Device Listing Information

Owner/Operator Number: 10055922

Registration Number: 3008903689

Listing No.	Product Code	Proper Name(s)	Registration Role
D304656	IQJ	Clavicle Splint	Manufacturer, Foreign Exporter
D304657	ILI	Shoulder/Arm Sling	
D304741	ISR	Lumbo-Sacral back brace	
D304742	IQK	Cervical collar	
D304743	ITQ	Hand Splint, knee brace	
D304744	ITW	Ankle, external brace	
D304745	FSD	Abdominal Binder	
D304746	ILG	Limb brace	
D333984	IPR	crutches	
D333985	IQI	elbow brace; hand braces; hip brace; foot brace	
D374922	LYU	Face Mask	
D381356	HOY	Goggles	
D381357	OEA	Isolation Gown	
D479790	CCX	Positioning Straps	
D488401	EXN	Hernia truss support	
D556004	MRI	Scoliosis Brace	