



✓ Facility

✓ Products Listing

## Annual Registration Successful

Facility: HUANGHUA PROMISEE DENTAL CO., LTD, Huanghua, Hebei, CHINA

You have successfully updated your registration and listing information for 2022.

Your registration will be valid through Dec 31, 2022.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2022.

**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](mailto:reglist@cdrh.fda.gov).

**The Owner/Operator Number for this Registration is: 10038868.**

### Facility Information

**Registration Number:**  
3009420946

**Initial Importer:**  
N

**Facility Name:**  
HUANGHUA PROMISEE DENTAL CO., LTD

**Legal Name:**

**Address:**  
Mould Industry Garden Empolder Section,  
Huanghua, Hebei, 061100, 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:**  
10038868

**Contact Name:**  
Qingxuan He

**Company:**  
HUANGHUA PROMISEE DENTAL CO., LTD

**Address:** Mould Industry Garden Empolder Section  
Huanghua, HEBEI, 061100, CHINA

**Telephone:**

86 - 0317 - 5261098

Fax:

86 - 0317 - 8881708

E-mail:

info@promiseedental.com

DUNS Number:

### Official Correspondent Information

Contact Name:

Diana Hong

Company:

Mid-link Consulting Co., Ltd

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Fax:

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jing.cheng@mid-link.net

DUNS Number:

### United States Agent Information

Contact First Name

Marco

Contact Last Name

Mu

Contact Title:

Mr

Business Name:

MID-LINK INTERNATIONAL, INC.

Address:

2219 Rimlang Drive, Suite 301  
Bellingham, Washington, 98226, UNITED STATES

Phone:

360 - 3257028

Fax:

360 -9253199

DUNS Number:

E-mail:

us.agent@mid-link.net

### Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Importers
D242979		510(k) exempt	KXR	APPLICATOR, RESIN	Manufacturer	
D135863		510(k) exempt	ERA	OTOSCOPE	Manufacturer	
D135862		510(k) exempt	KYX	DISPENSER, LIQUID MEDICATION	Manufacturer	

D135864		510(k) exempt	EAX	MIRROR, MOUTH	Manufacturer	
D286148		510(k) exempt	EGD	WAX, DENTAL, INTRAORAL	Manufacturer	
D209014		510(k) exempt	EIX	PROBE, PERIODONTIC	Manufacturer	US DENTAL DEPOT INC
D135861		510(k) exempt	KPY	Shield, protective, personnel	Manufacturer	
D135860		510(k) exempt	EGZ	Holder, film, x- ray	Manufacturer	
D233129		510(k) exempt	EHZ	Evacuator, oral cavity	Manufacturer	US DENTAL DEPOT INC
D209016	Enforcement Discretion		NSB	Patient personal hygiene kit	Manufacturer	US DENTAL DEPOT INC
D209015	Enforcement Discretion		NYG	Lapping tool kit	Manufacturer	US DENTAL DEPOT INC
D209018		510(k) exempt	EMG	FORCEPS, TOOTH EXTRACTOR, SURGICAL	Manufacturer	US DENTAL DEPOT INC
D135859		510(k) exempt	GAF	SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY	Manufacturer	
D135852		510(k) exempt	DYN	Mouthpiece, saliva ejector	Manufacturer	
D135851		510(k) exempt	EHY	TRAY, IMPRESSION, PREFORMED	Manufacturer	US DENTAL DEPOT INC
D135854		510(k) exempt	ECB	UNIT, SYRINGE, AIR AND/OR WATER	Manufacturer	
D135853		510(k) exempt	KXF	APPLICATOR, ABSORBENT TIPPED, NON- STERILE	Manufacturer	
D135856		510(k) exempt	EIF	ACCESSORIES, RETRACTOR, DENTAL	Manufacturer	
D135855		510(k) exempt	GED	BRUSH, DERMABRASION, MANUAL	Manufacturer	
D135858		510(k) exempt	KYW	CONTAINER, LIQUID MEDICATION, GRADUATED	Manufacturer	
D135857		510(k) exempt	DZN	INSTRUMENTS, DENTAL HAND	Manufacturer	

D451878		510(k) exempt	NDP	Accessories, implant, dental, endosseous	Manufacturer	
D242982		510(k) exempt	LRP	TRAY, SURGICAL	Manufacturer	
D242981		510(k) exempt	EIL	GAUGE, DEPTH, INSTRUMENT, DENTAL	Manufacturer	
D242980		510(k) exempt	EFL	FORCEPS, DRESSING, DENTAL	Manufacturer	
D451876		510(k) exempt	KHR	ABSORBER, SALIVA, PAPER	Manufacturer	
D364731		510(k) exempt	EHK	CUP, PROPHYLAXIS	Manufacturer	
D376158		510(k) exempt	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratic eyewear)	Manufacturer	
D376157		510(k) exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer	ITI Manufacturing Inc.
D216391		510(k) exempt	KMT	TRAY, FLUORIDE, DISPOSABLE	Manufacturer	US DENTAL DEPOT INC
D244971		510(k) exempt	EIY	INSTRUMENT, FILLING, PLASTIC, DENTAL	Manufacturer	
D136060		510(k) exempt	NRD	Unit, operative dental, accessories	Manufacturer	
D136061		510(k) exempt	FSM	TRAY, SURGICAL, INSTRUMENT	Manufacturer	US DENTAL DEPOT INC
D136059		510(k) exempt	IKX	AID, TRANSFER	Manufacturer	
D136058		510(k) exempt	ILS	ADAPTOR, HYGIENE	Manufacturer	

Date of Initial Registration: 2011-11-18 03:19:33.0