

FDA Establishment Registration — Device Listings

Source: Annual Registration Confirmation (2026) · Houli facility · Importer column omitted

Facility Information

Registration Number	3031369651
Facility Name	HSINER CO., LTD.
Address	No. 251, Sec.1, Houke Rd., Houli Dist., Taichung City, Taichung, 421, TAIWAN

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D405496	—	510(k) exempt	BZA	CONNECTOR, AIRWAY (EXTENSION)	Foreign Exporter; Manufacturer
E118248	—	510(k) exempt	CAE	AIRWAY, OROPHARYNGEAL, ANESTHESIOLOGY	Foreign Exporter; Manufacturer
E118246	—	510(k) exempt	BYG	MASK, OXYGEN	Manufacturer; Foreign Exporter
E118243	—	510(k) exempt	BSJ	MASK, GAS, ANESTHETIC	Foreign Exporter; Manufacturer
E120902	—	510(k) exempt	CAT	CANNULA, NASAL, OXYGEN	Foreign Exporter; Manufacturer
D112674	—	510(k) exempt	KGB	MASK, OXYGEN, NON-REBREATHING	Manufacturer; Foreign Exporter
D402403	—	510(k) exempt	BYX	TUBING, PRESSURE AND ACCESSORIES	Foreign Exporter; Manufacturer
E610171	K063268	—	BZD	Ventilator, non-continuous (respirator)	Foreign Exporter; Manufacturer
D153230	K120920	—	BZD	Ventilator, non-continuous (respirator)	Foreign Exporter; Manufacturer
D130813	—	Enforcement Discretion	OFP	Anesthesia breathing circuit kit (adult & pediatric)	Foreign Exporter; Manufacturer
D530428	—	510(k) exempt	BYH	DRAIN, TEE (WATER TRAP)	Foreign Exporter; Manufacturer
D530427	—	510(k) exempt	BTK	STRAP, HEAD, GAS MASK	Foreign Exporter; Manufacturer
D077722	—	510(k) exempt	BTC	BAG, RESERVOIR	Foreign Exporter; Manufacturer
D077721	—	510(k) exempt	BYD	CONDENSER, HEAT AND MOISTURE (ARTIFICIAL NOSE)	Foreign Exporter; Manufacturer
D014957	K052811	—	CAF	Nebulizer (direct patient interface)	Foreign Exporter; Manufacturer
E403388	K053466	—	BTM; BYE	Ventilator, emergency, manual (resuscitator); Attachment, breathing, positive end expiratory pressure	Foreign Exporter; Manufacturer

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D080035	K091185	—	CAH	Filter, bacterial, breathing-circuit	Foreign Exporter; Manufacturer
D014962	K070948	—	CAF	Nebulizer (direct patient interface)	Foreign Exporter; Manufacturer
E664684	—	510(k) exempt	BZO	SET, TUBING AND SUPPORT, VENTILATOR (W HARNESS)	Manufacturer; Foreign Exporter
E664683	—	510(k) exempt	CAI	Circuit, breathing (w connector, adaptor, y piece)	Foreign Exporter; Manufacturer
D058464	—	510(k) exempt	KFZ	HUMIDIFIER, NON-DIRECT PATIENT INTERFACE (HOME-USE)	Manufacturer; Foreign Exporter

Total listings: 21 · Registration/FEI 3031369651 · Generated for clear reprint (no Importer column; contact/PII omitted)