



## Fiscal Year 2026 FDA REGISTRATION INFORMATION

*To whom it may concern,*

**Establishment: Tomore Medical (Shenzhen) Co., Ltd**

**Registered Address:** Room 201, Building 1, Xiantaoyuan Industrial Zone, Silian Community, Henggang Street, Longgang District, Shenzhen Guangdong, 518000, China

**Registration Number: 3019414808**

**Owner/Operator Number: 10081686**

*has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, and the U.S. Agent information is:*

**U.S. Agent for FDA: SPICA MEDTECH CORP**

**Communications:** 1020 LINCOLN ST Denver, CO, 80203, United States

Phone: 720 6176666 Ext , Email: [fda.agent@spicagloble.com](mailto:fda.agent@spicagloble.com)

*Establishments that are involved in the production and distribution of medical devices intended for commercial distribution in the United States (U.S.), including those that are imported for export only, are required to register annually with the FDA under section 510(g) of the Federal Food, Drug, and Cosmetic Act; And annual registration for each fiscal year is required for all establishments. Annual registration shall take place during the period beginning on October 1 and ending on December 31 of each fiscal year.*

*The FDA does not issue registration certificates to medical device facilities nor does the FDA certify information for facilities that have registered their establishments and listed their medical devices.*

*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.*



For and on behalf of  
**EDTECH CORP**

Authorized Signature(s)

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<b>Listing No</b>	<b>Code</b>	<b>Device Name</b>
D443686	ESD	Hearing Aid(108(TE), 1108A(TE), 1108B(TE), 308(TE), 3308A(TE), 3308B(TE), 316(TE), 216(TE), 1208A(TE), 1208B(TE))
		Hearing Aid(APT818TE, IHP1216-IE, Lucid508, Lucid508-S, Lucid516 RIC, AT216, Eclarity mini, Eclarity LTE)
		Hearing Aid(5118DL(TE), 5118DH(TE), 5116DL(TE), 5116DH(TE), 5126H(TE), 5126L(TE), 5128H(TE), 5128L(TE), 5120L(TE))
		Hearing Aid(5116A(TE), 5116B(TE), 5216A(TE), 5216B(TE), 5216C(TE), 5116AE(TE), 5216AE(TE), 5118L(TE), 5118H(TE))
		Hearing Aid(5120H(TE), 5116L(TE), 5116H(TE), 816TE, ADR-816TE, APT818TE, APT516TE-RIC, APT616TE-RIC, ADR-816TE)
		Hearing Aid(Eclarity TE, 5222(TE), 5220(TE), 5003(TE), 5005(TE), 5006(TE), 5122(TE))
		Hearing Aid(1216AE(TE), 1216BE(TE), 1118(TE), 1120(TE), 1122(TE), 1124(TE), 7116T(TE), 7116(TE), 1216TE(TE), 508OE(TE))
		Hearing Aid(5007C, 5007E, 5008C, 5008T, 5220D, 6001, 6002, 6003, 6005, 6006)
D473073	OSM	Hearing Aid(5118DL(TE), 5118DH(TE), 5116DL(TE), 5116DH(TE), 5126H(TE), 5126L(TE), 5128H(TE), 5128L(TE), 5120L(TE))
		Hearing Aid(5120H(TE), 5116L(TE), 5116H(TE), 816TE, ADR-816TE, APT818TE, APT516TE-RIC, APT616TE-RIC, ADR-816TE)
		Hearing Aid(5116A(TE), 5116B(TE), 5216A(TE), 5216B(TE), 5216C(TE), 5116AE(TE), 5216AE(TE), 5118L(TE), 5118H(TE))
		Hearing Aid(APT818TE, IHP1216-IE, Lucid508, Lucid508-S, Lucid516 RIC, AT216, Eclarity mini, Eclarity LTE)
		Hearing Aid(1216AE(TE), 1216BE(TE), 1118(TE), 1120(TE), 1122(TE), 1124(TE), 7116T(TE), 7116(TE), 1216TE(TE), 508OE(TE))
		Hearing Aid(Eclarity TE, 5222(TE), 5220(TE), 5003(TE), 5005(TE), 5006(TE), 5122(TE))
		Hearing Aid(108(TE), 1108A(TE), 1108B(TE), 308(TE), 3308A(TE), 3308B(TE), 316(TE), 216(TE), 1208A(TE), 1208B(TE))
		Hearing Aid(5007C, 5007E, 5008C, 5008T, 5220D)
D490376	QUG	Hearing Aid(Eclarity TE, 5222(TE), 5220(TE), 5003(TE), 5005(TE), 5006(TE), 5122(TE))
		Hearing Aid(5116A(TE), 5116B(TE), 5216A(TE), 5216B(TE), 5216C(TE), 5116AE(TE), 5216AE(TE), 5118L(TE), 5118H(TE))
		Hearing Aid(5120H(TE), 5116L(TE), 5116H(TE), 816TE, ADR-816TE, APT818TE, APT516TE-RIC, APT616TE-RIC, ADR-816TE)
		Hearing Aid(1216AE(TE), 1216BE(TE), 1118(TE), 1120(TE), 1122(TE), 1124(TE), 7116T(TE), 7116(TE), 1216TE(TE), 508OE(TE))
		Hearing Aid(APT818TE, IHP1216-IE, Lucid508, Lucid508-S, Lucid516 RIC, AT216, Eclarity mini, Eclarity LTE)
		Hearing Aid(108(TE), 1108A(TE), 1108B(TE), 308(TE), 3308A(TE),

		3308B(TE), 316(TE), 216(TE), 1208A(TE), 1208B(TE))
		Hearing Aid(5118DL(TE), 5118DH(TE), 5116DL(TE), 5116DH(TE), 5126H(TE), 5126L(TE), 5128H(TE), 5128L(TE), 5120L(TE))
		Hearing Aid(SyncTune, SyncTune Pro, HearDot, HearDot Pro, 5130L, 5130H, 6130, 6127, 6129, Eclarity RIC)
D490377	QUF	Hearing Aid(1126, 1128, 6120, 6121, 6122, 6126, 6128, 5222, 5220, 5003, 5005, 5006, 5122)
		Hearing Aid(108, 1108A, 1108B, 308, 3308A, 3308B, 316, 216, 1208A, 1208B, 1216AE, 1216BE, 1118, 1120, 1122, 1124, 6116)
		Hearing Aid(IHP1216-IE, Lucid508, Lucid508-S, Lucid516 RIC, SuperMini-b, SuperMini-br, AT216, Eclarity mini)
		Hearing Aid(6116A, 6118, 7116T, 7116, 1216TE, 5001H, 5001L, 508OE, 5116A, 5116B, 5216A, 5216B, 5216C, 5116AE, 5216AE)
		Hearing Aid(Eclarity LTE, Eclarity TE)
		Hearing Aid(5118L, 5118H, 5118DL, 5118DH, 5116DL, 5116DH, 5126H, 5126L, 5128H, 5128L, 5120L, 5120H, 5116L, 5116H, 816TE)
		Hearing Aid(HearDot Pro, 5130L, 5130H, 6130, 6127, 6129, Eclarity RIC)
		Hearing Aid(3003, TE202, 5112, SyncTune, SyncTune Pro, HearDot)

**END OF THE ANNEX**