

Establishment Registration & Device Listing

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FDA listing

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Proprietary Name:	Easy Read Dual Mode Forehead Thermometer, Model TH091; Easy Read Dual Mode Thermometer, Model TH095; FT90; Non-Contact Clinical Thermometer, Model TH01BF; Non-Contact Clinical Thermometer, Model TH30F; Non-Contact Clinical Thermometer, Model TH36F; Non-Contact Clinical Thermometer, Model THB0F; Non-Contact Clinical Thermometer, Model THD2FA/THD2FE; Non-Contact Clinical Thermometer, Model THi0F; Non-Contact Forehead Thermometer, Model THD2FAE; Non-Contact Forehead Thermometer, Model THR0F; Non-contact Forehead Thermometer, MC-720; Precise Position Forehead Thermometer, Model TH104; Tommee Tippee Digital No Touch Thermometer, THD2FE	
Classification Name:	THERMOMETER, ELECTRONIC CLINICAL *	
Product Code:	<u>FLL</u>	
Device Class:	2	
Regulation Number:	<u>880.2910</u>	
Medical Specialty:	General Hospital	
Registered Establishment Name:	<u>KUNSHAN RADIANT INNOVATION CO., LTD.</u>	
Registered Establishment Number:	3004026659	
Premarket Submission Number:	<u>K121428</u>	
Owner/Operator:	<u>RADIANT INNOVATION, INC.</u>	
Owner/Operator Number:	9045429	
Establishment Operations:	Contract Manufacturer; Manufacturer	

5. Did you file under intended use code 081.006 [General Wellness Product] or other code ?

Ans: We don't use Intended use code, but we use product code. Kindly find the information below. Thank you!

Proprietary Name: Non-contact Forehead Thermometer, MC-720; Non-contact Forehead Thermometer, THMC2FE
Classification Name: THERMOMETER, ELECTRONIC, CLINICAL *****
Product Code: FLL
Device Class: 2
Regulation Number: 880.2910
Medical Specialty: General Hospital

By the way, we will have national holiday from April 2nd to 5th