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Establishment Registration & Device Listing

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Proprietary Name:	Model #15045; Model #15053; Thermo-Trace Infrared Thermometer
Classification Name:	THERMOMETER, ELECTRONIC, CLINICAL
Product Code:	FLL
Device Class:	2
Regulation Number:	880.2910
Medical Specialty:	General Hospital
Registered Establishment Name:	PRIZM MEDICAL, INC.
Registered Establishment Number:	1055808
Premarket Submission Number:	K012974
Owner/Operator:	PRIZM MEDICAL, INC.
Owner/Operator Number:	9005746
Establishment Operations:	Repackager/Relabeler

Page Last Updated: 08/17/2020

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U.S. Food and Drug Administration

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Device Classification Name	Thermometer, Electronic, Clinical
510(K) Number	K012974
Device Name	PRIZM MEDICAL INC. THERMOTRACE INFRARED THERMOMETER MODELS 15004 AND 15007
Applicant	PRIZM MEDICAL, INC. 5536 TROWBRIDGE DR. Dunwoody, GA 30338
Applicant Contact	Cathryn N Cambria
Correspondent	PRIZM MEDICAL, INC. 5536 TROWBRIDGE DR. Dunwoody, GA 30338
Correspondent Contact	Cathryn N Cambria
Regulation Number	880.2910
Classification Product Code	FLL
Date Received	09/05/2001
Decision Date	07/23/2002
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No