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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 PRIZM MEDICAL, INC. Name: Registered Establishment

1055808 Number: **Premarket Submission**

K012974 Number: Owner/Operator: PRIZM MEDICAL, INC.

9005746 Owner/Operator Number:

Contact FDA

Establishment Operations: Repackager/Relabeler

Page Last Updated: 08/17/2020

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Back To Search Results New Search **Device Classification** Thermometer, Electronic, Clinical Name 510(K) Number K012974 **Device Name** PRIZM MEDICAL INC. THERMOTRACE INFRARED THERMOMETER MODELS 15004 AND 15007 PRIZM MEDICAL, INC. Applicant 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 **FLL** Code Date Received 09/05/2001 **Decision Date** 07/23/2002 Decision Substantially Equivalent (SESE) Regulation Medical General Hospital Specialty 510k Review Panel General Hospital Summary Summary Traditional Type Reviewed By Third Party No Combination Product No