

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
1350 PICCARD DRIVE
ROCKVILLE, MD 20850

June 16, 2009

Reference: 0910270-000

Frank Lin
Quality Assurance Manager
RADIANT INNOVATION INC.
1F, NO. 3 INDUSTRIAL E. 9TH RD
SCIENCE-BASED INDUSTRIAL PARK
HSIN CHU, CHINA (TAIWAN) 30075

This is to acknowledge receipt of your June 10, 2009, document, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (title 21, code of Federal Regulations, Subchapter J) as they pertain to Initial Product Report requirements.

Your document has been assigned an accession number of 0910270-000, and has been classified as a(n) Initial Product Report (pursuant to Part 1002, Subpart B of the Regulation referenced above).

Further, the submittal has been assigned an informal subject title of "This submission is a(n) Initial Product Report. These Data Measurement, Transmit, Control Laser Products include designated model family TN0 with model(s) TN01U; model family TN2 with model(s) TN205L, TN253L, TN253LF, TN288L, TN288LF, TN288LT; model family TN3 with model(s) TN305LC; model family TN4 with model(s) TN400L, TN400L1, TN403L, TN408LC/LT, TN409LC, TN40ALC, TN40JLC; model family TN8 with model(s) TN806LCE, brand name ZyTemp. (See Rpt. for add'l models)."

This acknowledgement does not constitute approval of the document. You will be contacted if any questions or comments arise concerning your document.

Please note that your firm is required to submit an Annual Report to CDRH every year on September 1. This report may be prepared using CDRH's electronic submissions software, which can be downloaded at www.fda.gov/cdrh/cesub. You may also submit a paper Annual report, available online at www.fda.gov/cdrh/radhealth.

Thank you for your cooperation. If you have questions or comments, please write to the address above or call (240) 276-3332.

Sincerely Yours,

Robert Doyle
Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

Part 3. Current Production Tabulation

3.1 All Laser Products

Accession Number	Family Designation	Selling Model Numbers	Product Function	Class	Production Status		
					Active	Discont. (mo/yr)	Plant
0910270	TN0 Family	TN01U	Infrared Thermometer	II	X		KunShan CHINA
0910270	TN2 Family	TN205L, TN253L, TN253LF, TN288L, TN288LF, TN288LT	Infrared Thermometer	II	X		KunShan CHINA
0910270	TN3 Family	TN305LC	Infrared Thermometer	II	X		KunShan CHINA
0910270	TN4 Family	<p>TN40x Series: TN400L, TN400L1, TN403L, TN408LC, TN408LT, TN409LC, TN40ALC, TN40JLC, TN40B, TN40BLO, TN40BLA, TN40BLC</p> <p>TN410/TN41U Series: TN410L0(E), TN410L1(E), TN410L2(E), TN410L3(E), TN410L9(E), TN410LB(E), TN410LC(E), TN410LD(E), TN41U, TN41ULO, TN41UL3V, TN41ULCE</p> <p>TN418 Series: TN418L0(E), TN418L1(E), TN418L2(E), TN418L3(E), TN418L9(E), TN418LB(E), TN418LC(E), TN418LD(E)</p> <p>TN419 Series: TN419LB(E), TN419LC(E), TN419LD(E)</p> <p>TN42x Series: TN423LA(E), TN423LB(E), TN423LC(E), TN423LD(E), TN425LA(E), TN425LB(E), TN425LC(E)</p> <p>TN436 Series: TN436L0, TN436L1, TN436L2</p> <p>TN438 Series: TN438L0</p> <p>TN439 Series: TN439L0</p> <p>TN458 Series: TN458LC</p> <p>TN468 Series: TN468LC(E)</p>	Infrared Thermometer	II	X	<p>KunShan CHINA for all TN4 family</p> <p>HsinChu TAWAN For TN42x series</p>	
0910270	TN8 Family	TN806LCE	Infrared Thermometer	II	X		KunShan CHINA