



U.S. Food and Drug Administration
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SCIENCE-BASED, INDUSTRIAL PARK
HSINCHU, CHINA (TAIWAN) 30075

Reference: 2130967-000

This is to acknowledge receipt of your August 10, 2021, 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 Annual Report requirements.

Your document has been assigned an Accession Number of 2130967-000, and has been classified as a(n) Annual 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) Annual Report. These Data Measurement, Transmit, Control Laser Products cover the period from July 01, 2020 to June 30, 2021."

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

WARNING:

THE ACCESSION NUMBER ASSIGNED TO YOUR SUBMISSION DOES NOT IMPLY, CONVEY OR CONSTITUTE FDA APPROVAL OF ANY REPORT, APPLICATION FOR VARIANCE OR EXEMPTION, NOTIFICATION, OR ANY OTHER SUBMISSION OR ITS CONTENTS. THE ACCESSION NUMBER IS ONLY AN ACKNOWLEDGMENT THAT FDA HAS RECEIVED YOUR SUBMISSION. IT MAY BE REVOKED BY FDA. ITS DISCLOSURE IS YOUR RESPONSIBILITY. IT IDENTIFIES YOUR SUBMISSION FOR PRODUCTS OR PRODUCT FAMILIES IDENTIFIED IN THIS MESSAGE.

Be advised that failure to comply with FDA regulations may result in notification of affected persons and corrective actions at no cost to the purchaser, pursuant to 21 CFR Part 1003 -- Discovery of Defect or Failure to Comply and 21 CFR Part 1004 -- Repurchase, Repairs, or Replacement of Electronic Products.

Please be aware that the following CDRH Product Code(s) have been assigned to the product(s) described in this report:

RFR defined as Product Incorporating Certified Class 1 Laser Data Measurement, Transmit, Control Product

If these products will be shipped to the United States, the shipping broker will need to provide the full FDA Product Code at the time of entry, structured as follows:

95R- -FR

All Radiological Reports may be prepared using FDA's Electronic Submissions software which can be downloaded at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>. For more information on the FDA's eSubmitter program please see the following websites:

Radiological Health - <http://www.fda.gov/Radiation-EmittingProducts/default.htm>

Electronic Submissions (instead of paper reports) -
<http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>

FDA Electronic Submissions Gateway -
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

If you have any questions, please contact the Director of the Division of Radiological Health, or the branch chief of your respective product area, as listed on the CDRH Management Directory, under the Office of In Vitro Diagnostics and Radiological Health, Division of Radiological Health.
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm>

Please include a primary (and optional secondary) contact email address in all submissions (and/or cover letters) to facilitate electronic correspondence.

Sincerely yours,

Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

LASER PRODUCT/LASER LIGHT SHOW ANNUAL REPORT:

Part 1. Identification of Manufacturer

Report Date: Aug.10.2021

Company Name: **Radiant Innovation Inc.**

Address: **1F, No.3 , Industrial E. 9th Rd., Science-Based,**
Industrial Park, HsinChu, Taiwan 30075

Corresponding Official signature: **LynnChen**

Name & title: **Quality Assurance Manager**

Telephone: **+886 3 6111666 ext: 8123**

Firm name & address, if different from above:

Factory Name: **KunShan Radiant Innovation Co., Ltd.**

Address : **No.20, TaiHong Road, WuSongJiang Development Zone,**
YuShan Town, KunShan City, JiangSu, CHINA

This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period July 1, 2020 through June 30, 2021.

Part 2. Production Status

- (X) Products were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.
- () No products were manufactured during this period but the firm is still in business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.
- () No products were manufactured during this period and the firm is now out of business. If you check this, complete Part 6 and mail pages 1 and 4.
- () Products were manufactured during this period but the firm is now out of business. If you check this, complete and mail this entire report.

LASER PRODUCT/LASER LIGHT SHOW ANNUAL REPORT:

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
0910270-000	TN0 Family	TN01U	Infrared Thermometer	II	X		KunShan CHINA
0910270-000	TN2 Family	TN205L,TN253L,TN253LF, TN288L,TN288LF,TN288LT	Infrared Thermometer	II	X		KunShan CHINA
0910270-000	TN3 Family	TN305LC	Infrared Thermometer	II	X		KunShan CHINA
0910270-000	TN4 Family	<p>TN40x Series: TN400L,TN400L1,TN403L, TN408LC,TN408LT,TN409LC, TN40ALC,TN40BL0,TN40BLA, TN40BLC, TN40J</p> <p>TN410/TN41U Series: TN410L0(Y/Z)(G)(E), TN410L1(E)(Y)(G) (E), TN410L2(G)(E), TN410L3(G)(E), TN410LA(G)(E), TN410L9(G)(E), TN410LB(Y)(G)(E), TN410LC(Y)(G)(E), TN410LD(Y/Z)(G)(E), TN41UL0,TN41UL3V, TN41ULCE, TN41ULB(V)(E),TN41UL3</p> <p>TN418 Series: TN418L0(Y/Z)(G)(E), TN418L1(Y)(G)(E), TN418L2(G)(E), TN418L3(G)(E), TN418L9(G)(E), TN418LB(Y)(G)(E), TN418LC(Y)(G)(E), TN418LD(Y/Z)(G)(E), TN418LA(G)(E), TN418L1U(Y)(G),TN418LR, TN418LCR(V)(G)</p> <p>TN419 Series: TN419LB(E),TN419LC(E), TN419LD(E)</p> <p>TN42x Series: TN423LA(E),TN423LB(E), TN423LC(E),TN425LA(E), TN425LB(E),TN425LC(E), TN425L(E),TN425LN(E), TN425LM(E),</p> <p>TN436 Series: TN436L0(Y),TN436L1(Y), TN436L2(Y)</p>	Infrared Thermometer	II	X	<p>KunShan CHINA for all TN4 family</p> <p>HsinChu TAIWAN For TN42x series and TN47X series</p>	

0910270-000	TN4 Family	TN438 Series: TN438L0 TN439 Series: TN439L0 TN458 Series: TN458LC TN468 Series: TN468LC(E) TN430 Series: TN430LC(Y), TN430L0(Y), TN430L1(Y), TN430L2(Y), TN47x Series: TN475LC(E)	Infrared Thermometer	II	X		KunShan CHINA for all TN4 family HsinChu TAIWAN For TN42x series and TN47X series
0910270-000	TN8 Family	TN806LCE	Infrared Thermometer	II	X		KunShan CHINA
0910270-001	TN5 Family	TN568LC0, TN568LC1, TN568LC2 TN568LC0U, TN568LC1U, TN568LC2U,	Infrared Thermometer	II	X		HsinChu TAIWAN
0910270-001	TN5 Family	TN568HC0, TN568HC1, TN568HC2, TN568HC0U, TN568HC1U, TN568HC2U,	Infrared Thermometer	IIIa	X		HsinChu TAIWAN
0910270-002	TN4 Family	TN498 Series: TN498LB(Y)(E), TN498LC(Y)(E), TN498LD(Y)(E), TN498L1(Y)(E) TN499 Series: TN499LB(Y)(E), TN499LC(Y)(E), TN499L1(Y)(E), TN499L5(Y)(E), TN499LD(Y)(E), TN43C Series: TN43CL2(Y),TN43CL0 (Y), TN43CL3(Y) TN41M Series: TN41ML0(Y)(G), TN41ML1(Y)(G), TN41MLB(Y)(G), TM41MLD(Y)(G),	Infrared Thermometer	II	X		KunShan CHINA for all TN4 family
0910270-002	TN7 Family	TN768 Series: TN768LB, TN768LC, TN768LB(U), TN768LC(U),	Infrared Thermometer	II	X		HsinChu TAIWAN
0910270-003	TN2 Family	TN205L1,	Infrared Thermometer	II	X		KunShan CHINA
0910270-003	TN5 Family	TN568LC0U, TN568LC1U, TN568LC2U	Infrared Thermometer	II	X		KunShan CHINA
0910270-003		TN568HC0U, TN568HC1U, TN568HC2U	Infrared Thermometer	IIIa	X		KunShan TAIWEN
0910270-003	TN7 Family	TN768 series : TN768LB(U), TN768LC(U), TN768LB, TN768LC TN758 series : TN758LC(U)(K)(G), TN758LB(U)(K)(G)	Infrared Thermometer	II	X		HsinChu TAIWAN
0910270-003	TCT Family	TCT401L, TCT402L TCT703F,	Thermo-couple Thermometer	II	X		KunShan CHINA
0910270-003	TN4 Family	TN499L5X	Infrared Thermometer	IIIa	X		KunShan CHINA
0910270-003		TN410L1(W/X/H) (G)(E)	Infrared Thermometer	IIIa	X		KunShan CHINA

0910270-003	TN4 Family	<p>TN497 Series: TN497LB(Y)(E), TN497LC(Y)(E), TN497LD(Y)(E), TN496 Series: TN496LB(Y)(E), TN496LC(Y)(E), TN496LD(Y)(E), TN49R Series: TN49RLC(Y),TN49RLD(Y) TN49RLB(Y) TN433 Series: TN433L0(Y),TN433L1(Y), TN433L2(Y) TN41A Series: TN41ALB(Y)(G), TN41ALC(Y)(G), TN41ALD(Y)(G), TN41AL2(Y)(G), TN41AL3(Y)(G),TN41AL3B TN43S Series: TN43SL2(Y), TN43SL1(Y) TN43P series : TN43PL1(Y),TN43PL2(Y) TN49S series : TN49SLBU(Y)(G), TN49SLCU(Y)(G)</p>	Infrared Thermometer	II	X		<p>KunShan CHINA for all TN4 family</p> <p>HsinChu TAIWAN For TN42x series</p>
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0910270-003	TN4 Family	<p>TN410/TN41U Series: TN410LOW/X(G)(E), TN410L1(W/X/H)(G)(E), TN410L2X(G)(E), TN410L3X(G)(E), TN410LBX(G)(E), TN410LCW/X(G)(E), TN410LDX(G)(E), TN410L9H(G)(E), TN41ULCE(G)X</p> <p>TN418 Series: TN418L0X(G)(E), TN418L1W/X(G)(E), TN418L2X(G)(E), TN418L3X(G)(E), TN418L9X(G)(E), TN418LBX(G)(E), TN418LCW/X(G)(E), TN418LDX(G)(E),TN418L1UX(G), TN418LCR(V)(X/H)(G)</p> <p>TN41M Series: TN41ML0W/X(G), TN41ML1W/X(G), TN41MLBX(G),TM41MLDX(G), TN41ML1GH</p> <p>TN43 Series: TN430LC(X/H),TN436L2(X/H)</p> <p>TN498 Series: TN498LB(X/H)(E), TN498LC(W/X/H)(E), TN498LD(X/H)(E), TN498L1(W/X/H),TN498LTX</p> <p>TN497 Series: TN497LB(X/H)(E), TN497LC(W/X/H)(E), TN497LD(X/H)(E),</p> <p>TN496 Series: TN496LB(X/H)(E), TN496LC(W/X/H)(E), TN496LD(X/H)(E),</p> <p>TN499 Series: TN499LBX(E), TN499LDX(E), TN499LC(W/X/H)(E), TN499L1(W/X/H)(E), TN499L2X(E), TN499L5X</p> <p>TN41A Series: TN41ALB(G)X,TN41ALC(G)W/X, TN41ALD(G)X,TN41AL1(G)W/X , TN41AL2(G)X,TN41AL3(G)X</p> <p>TN43P series : TN43PL1X,TN43PL2X, TN43PL1H, TN43PL2H</p>	Infrared Thermometer	IIIa	X		KunShan CHINA
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0910270-003	TN4 Family	TN49S series : TN49SLBU(W/X/H)(G), TN49SLCU(W/X/H)(G) TN42x Series: TN423LAX(E),TN423LBX(E), TN423LCX(E),TN425LAX(E), TN425LBX(E),TN425LCX(E), TN425LX(E),TN425LNX(E), TN425LMX(E), TN425LM(X)(E)(EMS) TN43x Series: TN43UL1(X/H),TN43ULC(X/H)	Infrared Thermometer	IIIa	X		HsinChu TAIWAN
0910270-004	TCT Family	TCT703L(E), TCT703LF(E), TCT70MF	Thermo-couple Thermometer	II	X		KunShan CHINA
0910270-004	TCT Family	TCT703X(E),TCT703XF(E),	Thermo-couple Thermometer	IIIa	X		KunShan CHINA
0910270-004	TN4 Family	TN40J,TN4U8	Infrared Thermometer	II	X		KunShan CHINA
0910270-005	TCT Family	TCT28 Series: TCT28	Thermo-couple Thermometer	II	X		KunShan CHINA
0910270-006	TN4 Family	TN418 Series: TN418LCR(V)(G)	Infrared Thermometer	II	X		HsinChu TAIWAN
	TCT Family	TCT35W Series: TCT35W, TCT35WV, TCT35WB TCT35WN	Thermo-couple Thermometer	II	X		KunShan CHINA
	TN4 Family	TN4U8 Series: TN4U8LRX, TN4U8LBRX TN4U8LAX	Infrared Thermometer	IIIa	X		KunShan CHINA
0910270-007	TN4 Family	TN433 Series: TN433L1X/H, TN433L0X/H, TN433L2X/H TN43C Series: TN43CL0X/H, TN43CL1X/H, TN43CL3X/H TN41A Series: TN41ALCH, TN41AL3H TN430 Series: TN430L0(X/H), TN430L1(X/H), TN430L2(X/H) TN436 Series: TN436L0(X/H),, TN436L1(X/H), TN43P Series: TN43PL1X, TN43PL2X TN49R Series: TN49RXCG, TN49XCUG, TN49RXG,TN49RXUG, TN49RXBG	Infrared Thermometer	IIIa	X		KunShan CHINA

0910270-008	TCT Family	TCT703 Series: TCT703LF2(E),TCT703LB(E), TCT703LFB(E),TCT703L(E), TCT703LF(E), TCT703F,	Thermo- couple Thermometer	II	X		KunShan CHINA
0910270-009							
0910270-008	TCT Family	TCT703 Series: TCT703X(E),TCT703XF(E), TCT703XF2(E),TCT703XB(E), TCT703XFB(E), TCT703XF2B(E), TCT703XF(B:PMS 109C,P:Black), TCT703XF(C:PMS136C,P:PMS 286C),TCT703XF2(B:PMS Black), TCT703LF2B(E)	Thermo- couple Thermometer	IIIa	X		KunShan CHINA
0910270-009							
0910270-010	TN4 Family	TN418 Series: TN418LCR(V)(G) TN49S Series: TN49SLBUYG, TN49SLCUYG	Infrared Thermometer	II	X		KunShan CHINA
	TN4 Family	TN418 Series: TN418LCR(V)X(G), TN410 Series: TN410L1H(G)(E), TN498 Series: TN498LCH(E) TN430 Series: TN430LOH,TN430L1H, TN430L2H, TN430LCH TN436 Series: TN436LOH,TN436L1H TN43P Series: TN43PL1H, TN43PL2H TN43 Series: TN43UL1X,	Infrared Thermometer	IIIa	X		KunShan CHINA
0910270-011	TN4 Family	TN498 Series: TN498LTH	Infrared Thermometer	IIIa	X		KunShan CHINA
	TCT Family	TCT7 Series: TCT70MF	Infrared Thermometer	II	X		KunShan CHINA
0910270-012	TN4 Family	TN423 Series: TN423LCH(E) TN49A Series: TN49ALA, TN49ALB, TN49ALAF, TN49ALBF	Infrared Thermometer	IIIa	X		KunShan CHINA/