

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

February 9, 2009

Reference: 0112298-008

Jessica Chang

Prodigy Technology Consultant Co., Ltd.  
1F No. 181, Sec 2  
Wunhua 1st Rd. Linkou Township  
Taipei, CHINA (TAIWAN) 24457

This is to acknowledge receipt of your January 21, 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 0112298-008, 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 supplement. These Data Measurement, Transmit, Control Laser Products include designated model family Laser Optic Transceiver Module with model(s) BTR-X1X2X3X4X5X6X7X8X9X10-XXXXXXG, BTRS-X1X2X3X4X5X6X7X8X9X10-XXXXXXG, GBX0-X1X2X3X4X5X6X7X8X9X10-XXXXXXG, brand name Optoway. (See Rpt. for add'l models) (For Optoway Technology Inc).".

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](http://www.fda.gov/cdrh/cesub). You may also submit a paper Annual report, available online at [www.fda.gov/cdrh/radhealth](http://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

cc: P.C. Chen  
OPTOWAY TECHNOLOGY INC  
38, KUANG FU SOUTH ROAD  
HU KOU, HSIN CHU IND PARK  
HSIN CHU, CHINA (TAIWAN) 303

PART 2: PRODUCT AND MODEL IDENTIFICATION

2.1 List all names, brand names, model numbers and model family designations of the laser product being reported. If the product is sold by other companies under different brand names, also give the names and addresses of the companies, the brand names, and the model numbers, and indicate how the brand names and model numbers correspond with your own brand names and model numbers.

ADDING LASER OPTIC TRANSCEIVER MODULE:

Company Name	OPTOWAY TECHNOLOGY INC.
Brand Name	OPTOWAY

Item	OPTOWAY Model Numbers / Family	Attached data sheet for representation
1	BTR-X <sub>1</sub> X <sub>2</sub> X <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> X <sub>7</sub> X <sub>8</sub> X <sub>9</sub> X <sub>10</sub> -XXXXXXG	BTR-3620G
2	BTRS-X <sub>1</sub> X <sub>2</sub> X <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> X <sub>7</sub> X <sub>8</sub> X <sub>9</sub> X <sub>10</sub> -XXXXXXG	BTRS-7640CG
3	GBX <sub>0</sub> -X <sub>1</sub> X <sub>2</sub> X <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> X <sub>7</sub> X <sub>8</sub> X <sub>9</sub> X <sub>10</sub> -XXXXXXG	GBS-9010FG
4	SPX <sub>0</sub> -X <sub>1</sub> X <sub>2</sub> X <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> X <sub>7</sub> X <sub>8</sub> X <sub>9</sub> X <sub>10</sub> -XXXXXXG	SPS-8105WG
5	TRX <sub>0</sub> -X <sub>1</sub> X <sub>2</sub> X <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> X <sub>7</sub> X <sub>8</sub> X <sub>9</sub> X <sub>10</sub> -XXXXXXG	TRM-5101G
6	TRXL-X <sub>1</sub> X <sub>2</sub> X <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> X <sub>7</sub> X <sub>8</sub> X <sub>9</sub> X <sub>10</sub> -XXXXXXG	TRSL-3380G
7	XPX <sub>0</sub> -X <sub>1</sub> X <sub>2</sub> X <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> X <sub>7</sub> X <sub>8</sub> X <sub>9</sub> X <sub>10</sub> -XXXXXXG	XPS-2110WG
8	SPL-Y <sub>1</sub> Y <sub>2</sub> Y <sub>3</sub> Y <sub>4</sub> Y <sub>5</sub> Y <sub>6</sub> -XXXXXXG	SPL-94B73B-WG
9	LT-Y <sub>1</sub> Y <sub>2</sub> Y <sub>3</sub> Y <sub>4</sub> Y <sub>5</sub> Y <sub>6</sub> -XXXXXXG	LT-54B33B-PG
10	Y <sub>7</sub> NUY <sub>8</sub> -Y <sub>1</sub> Y <sub>2</sub> Y <sub>3</sub> Y <sub>4</sub> Y <sub>5</sub> Y <sub>6</sub> -XXXXXXG	NU-73B94B-PG

Parameter	Coding
X0	B, L, M, S or any alphanumeric character
X1	0, 1, ..., 9
X2	0, 1, ..., 9
X3	1, 2, ..., 9, Blank, or any alphanumeric character
X4	0, 1, ..., 9
X5	0, 1, ..., 9
X6	A, B, Blank, or any alphanumeric character
X7	F, T, L, Blank, or any alphanumeric character
X8	C, F, M, V, Blank, or any alphanumeric character
X9	W, Z, Blank, or any alphanumeric character
X10	E, Blank, or any alphanumeric character
Y1	0, 1, ..., 9
Y2	0, 1, ..., 9
Y3	B, C, D, E, H, or any alphanumeric character
Y4	0, 1, ..., 9
Y5	0, 1, ..., 9
Y6	B, C, D, E, H, or any alphanumeric character
Y7	H, O, Blank, or any alphanumeric character
Y8	V, Blank, or any alphanumeric character
X	Blank or any alphanumeric character