

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND  
RADIOLOGICAL HEALTH  
10903 New Hampshire Avenue  
WO66-4617  
Silver Spring, MD 20993

September 18, 2009

Reference: 0910410-000

Jeanne Han  
Safety Engineer  
Bay Area Compliance Laboratories Corp.  
1274 Anvilwood Avenue  
Sunnyvale, CA 94089

This is to acknowledge receipt of your September 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 0910410-000, 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 Multi-wavelength Laser Source with model(s) FHS2T01/LS-201t, Brand Name F2H/PRO. (For Sh. Guangjia Instruments Co., Ltd.)."

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 by September 1.

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>

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

Thank you for your cooperation. If any questions or concerns arise during our review of your report, we will notify you. If you have any questions, contact us at (301) 796-5710.

Sincerely Yours,

Robert J. Doyle  
Electronic Products Branch  
Division of Mammography Quality and Radiation Programs  
Office of Communication, Education, and Radiation Programs  
<http://www.fda.gov/Radiation-EmittingProducts/default.htm>

cc: Liu Peng  
SH. GUANGJIA INSTRUMENTS CO., LTD  
6F, XIN'AN BLD. 99 TIANZHOU RD  
NEW-TECH DEVP. ZONE CAOHEJING  
SHANGHAI, CHINA

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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 Multi-wavelength laser with model(s) FHS2D02/LS-202D, FHS2D03/LS-203D, Brand Name F2H/PRO. (For Sh. Guangjia Instruments co., Ltd).".

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September 18, 2009

Reference: 0920392-000

Jeanne Han  
Safety Engineer  
Bay Area Compliance Laboratories Corp.  
1274 Anvilwood Avenue  
Sunnyvale, CA 94089

This is to acknowledge receipt of your September 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 Model Change Product Report requirements.

Your document has been assigned an accession number of 0920392-000, and has been classified as a(n) Model Change 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) Model Change Product Report. These Data Measurement, Transmit, Control Laser Products include designated model family Mini Dual-wavelength Laser Source with model(s) FHS1D02/LS-102D, FHS1D03/LS-103D, Brand Name F2H/PRO. (For Sh. Guangjia Instruments Co., Ltd.)."

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