U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Sometech Incorporated 4/6/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

April 6, 201

VIA United Parcel Service

Mr. Hee-Bong Yang
President
Sometech Incorporated
152-050 2nd Floor
Byuksan Digital Valley III
212-13 Gurodong, Gurogu, Seoul
Korea, Republic of (South)

Dear Mr. Yang:

During an inspection of your firm located in Seoul, Republic of South Korea, on November 1, 2010, through November 4, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures medical imaging equipment and high-frequency surgical instruments. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820.

We received a response from you dated November 23, 2010,concerning our investigator's observations noted on the Form FDA 483, List of Inspectiona Observations, that was issued to you. We address this response below, in relation to each of the noted violations. Also included are observations discussed with you during the inspection. These violations include, but are not limited to, the following:

1. Failure to adequately establish and maintain procedures for implementing corrective and preventative actions, as required by 21 CFR 820.100 (a). For example:

(a) SQP14A Rev 7 "Correct and Precaution Action" dated June 04, 2010, SQP05-1 Rev 0 "**(b)(4)** Analysis Procedure" dated January 15, 2007, and/or SQP14A-2 Rev 4 "Correction Action Request **(b)(4)**":

i. Do not include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Also, QSP14 A Rev 7 does not define that appropriate statistical methodology should be employed where necessary to detect recurring quality problems;

ii. Do not include requirements for identifying the actions needed to prevent recurrence of non-conforming product and other quality problems;

iii. Do not include requirements for verifying or validating the corrective and preventive action to ensure that such action does not adversely affect the finished device;

iv. Do not include requirements for implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; and

v. Do not include requirements for ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

(b) SQP05-1 Rev 0 defines that service records and complaints are summarized **(b)(4)**, but does not define the procedure for analysis across quality data sources.

(c) All five CAPAs initiated in 2009 and 2010 for US devices were reviewed and found deficient:

CAPA #: (b)(4), Date: May 13, 2010
Identified by: **(b)(4)**

Device: Lysos
Nonconformity: **(b)(4)**
Corrective Action Needed: Not complete
Verification: Not done
Implementation and recording changes: Not done

CAPA #: (b)(4), Date: May 03, 2010
Identified by: **(b)(4)**
Device: Dr. Oppel
Nonconformity: **(b)(4)**
Corrective Action Needed: Not complete
Verification: Not done
Implementation and recording changes: Not done

CAPA #: (b)(4), Date: February 05, 2010
Identified by:**(b)(4)**
Device: Dr. Camscope
Nonconformity: **(b)(4)**
Corrective Action Needed: No data
Verification: Not done
Implementation and recording changes: No data

CAPA #: (b)(4), Date: January 07, 2010
Identified by:**(b)(4)**
Device: Dr. Oppel
Nonconformity: **(b)(4)**
Corrective Action Needed: Not complete
Verification: Not done
Implementation and recording changes: Not done

CAPA #: (b)(4), Date: None
Identified by: **(b)(4)**
Device: Dr. Highscope
Nonconformity: **(b)(4)**
Corrective Action Needed: Not complete
Verification: N/A
Implementation and recording changes: Not done

(d) CAPA No. **(b)(4)** dated September 03, 2009, was approved prior to the completion of implementing and recording changes in methods an procedures needed to correct and prevent identified problems. The investigation of the nonconformity cause determined that the supplier of the bracket used in the manufacture of Dr. Highscope did not meet specifications. As a result, in accordance with SQI01 Rev 13 Incoming Inspectio Procedure dated September 01, 2010, the firm should add the bracket to the list of receiving acceptance activities. However, this action was no completed as of November 04, 2010.

The adequacy of your response dated November 23, 1010 cannot be determined at this time. You summarized revisions for your procedures:

SQP14A – Corrective and Preventive Action Procedure
SQP20B – **(b)(4)**
SQI01 – Incoming Inspection Manual

However, a copy of the procedures showing their implementation was not included in the response.

2. Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example,

(a) The complaint handling procedure, SQP14A Rev 7 "Correct and Precaution Action" dated June 04, 2010, Section 7.2:

i. Does not ensure that all complaints are processed in a uniform and timely manner; oral complaints are documented upon receipt, and complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803, Medical Device Reporting.

ii. Does not provide that all complaints should be reviewed and evaluated to determine whether an investigation is necessary. Also, SQP14A Rev 7 Section 7.2 does not provide that when no investigation is made, the manufacturer should maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

iii. Does not provide that any complaint involving the possible failure of the device, labeling, or packaging to meet any of its specifications should be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

iv. Does not provide that complaints representing events that are MDR reportable should be promptly reviewed, evaluated, and investigated by a designated individual; maintained in a separate portion of the complaint files; and clearly identified.

v. Does not provide that records of investigations should include the requirements defined under 21 CFR 820.198(e)(1)-(8).

(b) All **(b)(4)** complaints received in 2009 and 2010 for US devices were reviewed and found deficient. For example,

i. Complaint No.**(b)(4)** dated February 11, 2010, does not include the date the complaint was closed; the name, address, and phone number of the complainant; the dates of the investigation; and any reply to the complainant.

ii. Service Report No. **(b)(4)** dated March 17, 2010, was issued in response to **(b)(4)** nonconforming devices:**(b)(4)** devices were reported to have light leakage due to damaged fiber and **(b)(4)** device was reported to have an unclear image due to a faulty camera sensor. These complaints:

- Were not processed through your firm's complaint handling process and did not include any documentation ensuring the complaints were evaluated to determine whether they represent an MDR reportable event;

- Did not include the dates the complaints were received; any device identification(s) and control number(s) used; the names, addresses, and phone numbers of the complainants; the dates of the investigations; and any replies to the complainants.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP14A - Corrective and Preventive Action Procedure, Section 7.2; however, a copy of the procedure showing its implementation was not included in the response.

3. Failure to establish and maintain adequate procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented, as required by 21 CFR 820.30(c). For example:

(a) The design inputs procedure, SQP04 Rev 10 "Design and Development Procedure" dated July 24, 2008, Section 3.2.1, does not provide that design inputs should be reviewed and approved by a designated individual(s). Also, SQP04 Rev 10 Section 3.2.1 does not provide that the approval includes the date the individual(s) approving the requirements shall be documented.

(b) Your firm did not document the first set of design inputs for the LVT100 design project.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP04 – Designs and Developing Management Procedure, Section 3.2.1; however, a copy of the procedure showing its implementation was not included in the response.

4. Failure to establish and maintain adequate procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, as required by 21 CFR 820.30(d). For example:

(a) Your firm's design output procedure, SQP04 Rev 10 "Design and Development Procedure" dated July 24, 2008, Section 3.5.2

i. Does not adequately state procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements;
ii. Does not contain or make reference to acceptance criteria and does not ensure that those design outputs that are essential for the proper functioning of the device are identified;
iii. Does not provide that design output should be documented, reviewed, and approved before release; and
iv. Does not provide that the approval, including the date and signature of the individual(s) approving the output, should be documented.

(b) The following design outputs for the LVT100 design project did not include the date of the individual(s) approving the output:

i. SQP04-5 Rev 1 "**(b)(4)**" dated July 21, 2008;
ii. SQP04-5 Rev 1 "**(b)(4)**" dated July 21, 2008;
iii. DQP04-7 Rev 1 "Approval of Parts" dated April 14, 2009;
iv. Dwg. No. M103M00434 Rev 0 "**(b)(4)**" dated June 10, 2008;
v. SQP04-4 Rev 0 "**(b)(4)**" dated January 11, 2008; and
vi. "**(b)(4)**" Rev 0 "**(b)(4)**" dated July 21, 2008.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP04 – Designs and Developing Management Procedure, Section 3.5.2; however, a copy of the procedure showing its implementation was not included in the response.

5. Failure to establish and maintain adequate procedures to ensure that formal documented reviews of the design results are planned and conducted a appropriate stages of the device's design development and ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed, as required in 21 CFR 820.30(e). For example:

(a) The design review procedure, SQP04 Rev 10 "Design and Development Procedure" dated July 24, 2008, Section 3.4 does not adequately ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed.

(b) Your firm provided SQP(production)-10 Rev 0 "Meeting" dated July 20, 2008, as the final design review meeting for the LVT100 design project. This design review:

i. Did not include an individual who does not have direct responsibility for the design stage being reviewed; and

ii. Was conducted prior to the manufacture of any design validation activities (no LVT100 devices were manufactured at this time).

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP04 – Designs and Developing Procedure, Section 3.4; however, a copy of the procedure showing its implementation was not included in the response.

6. Failure to establish and maintain adequate procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF, as required by 21 CFR 820.30(f). For example:

(a) Your firm's design verification procedure, SQP04 Rev 10 Design and Development Management dated June 24, 2008;

i. Does not provide that design verification should confirm that the design output meets the design input requirements; and

ii. Does not provide that the results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, should be documented in the DHF.

(b) Your firm provided SQP04-2 Rev 2 "Design Verification **(b)(4)**" dated August 09, 2008, as the only design verification activity conducted for the LVT100 design project.

i. A protocol was not established prior to the conducting of any design verification activities.

ii. SQP04-2 Rev 2 does not include the date and the individual(s) performing the verification.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP04 – Designs and Development Management Procedure; however, a copy of the procedure showing its implementation was not included in the response.

7. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). For example:

(a) Your firm's design validation procedure, SQP04 Rev 10 "Design and Development Management" dated June 24, 2008, Section 3.8, does not adequately define procedures for validating the device design. For example, SQP Rev 10 Section 3.8:

i. Does not provide that design validation shall be performed under defined operating conditions on initial production units, lost, or batches, or their equivalents;

ii. Does not provide that design validation should ensure that devices conform to defined user needs and intended uses and should includ testing of production units under actual or simulated use conditions; and

iii. Does not provide that the results of the design validation, including identification of the design, method(s), the date, and the individua (s) performing the validation, should be documented in the DHF.

(b) Your firm provided "Device Inspection Record" dated October 11, 2007, and Report No. SV-25 Rev 0 "Software Validation Report" dated Ma 30, 2008 as the only two design validations conducted for the LVT100 design project.

i. "Device Inspection Record" and Report No. SV-25 Rev 0 do not reference the serial numbers of the LVT100s used in the validation activities. Therefore, your firm was unable to demonstrate that these design validation activities were performed on initial production units, lots, or batches, or their equivalents. Although the person responsible stated that initial production units were used in both validations, DHRs were not maintained.

ii. Your firm did not develop any validation protocols for "Device Inspection Record" and Report No. SV-25 Rev 0.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP04 – Designs and Development Procedure, Section 3.8; however, a copy of the procedure showing its implementation was not included in the response.

8. Failure to establish and maintain adequate procedures for the identification, documentation, validation or where appropriate verification, review, an approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example:

(a) Your firm's design changes procedure does not adequately define procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of both pre- and post- production design changes before their implementation.

(b) Your firm did not adequately document and implement procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation. For example,

i. Pre-production design change no. 080710-01 dated July 10, 2008, involved removing your firm's logo from the LVT100 case. There is no documentation of any validation or verification activities and the dates of review and approval of the design change before its implementation.

ii. SQP04-13 Rev 0 "**(b)(4)**" dated March 13, 2009, was provided by your firm as the only post-production design change for the LVT-100 design project. This design change record did not contain any identification and validation or where appropriate verification. Also, the review an approval of design changes before their implementation were not dated.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP04 – Designs and Development Procedure; however, a copy of the procedure showing its implementation was not included in the response.

9. Failure of the manufacturer to establish and maintain an adequate design history file that contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part, as required by 21 CFR 820.30(j). For example, approved drawings of parts used in the manufacture of LVT100 were not included in the design history file for the LVT100 design project.

You have not had the opportunity to provide a response since this violation was not listed on the FDA 483 as an observation.

10. Failure to establish and maintain adequate procedures to control environmental conditions, where environmental conditions could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, your firm did not establish procedures for monitoring their electrostatic discharge devices used during the handling of, among other things, printed circuit boards.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP09B - Process Management Procedure; however, a copy of the procedure showing its implementation was not included in the response.

11. Failure to establish and maintain adequate acceptance procedures, where appropriate, to ensure that specified requirements for in-process produc are met, as required by 21 CFR 820.80(c).For example, your firm did not validate the soldering process used in the manufacture of Dr. Oppel ST-501 device. There are **(b)(4)** manufacturing steps requiring the use of a **(b)(4)**. The justification provided for not conducting any validation activities for this process was that after each **(b)(4)** operation, the operation would be verified by **(b)(4)** (e.g.,**(b)(4)**, etc.).

You have not had the opportunity to provide a response since this violation was not listed on the FDA 483 as an observation.

12. Failure to establish and maintain adequate procedures to document acceptance activities, as required by 21 CFR 820.80(e). For example, your firm does not define, document, and implement procedures for verification activities to include the name of the individual conducting the verification activit and the date the activity was conducted.

You have not had the opportunity to provide a response since this violation was not listed on the FDA 483 as an observation.

13. Failure of the manufacturer to establish and maintain adequate procedures to ensure that equipment next calibration dates are documented and displayed on or near each piece of equipment, as required by 21 CFR 820.72(b)(2). For example, the ST-QC-02 **(b)(4)** did not display the next calibration date.

You have not had the opportunity to provide a response since this violation was not listed on the FDA 483 as an observation.

14. Failure to establish and maintain adequate procedures to ensure that sampling methods are adequate for their intended use, as required by 21 CFI 820.250(b). For example, the firm was unable to provide a statistical rationale for sampling **(b)(4)** LVT100 units used in the validation activities to comply with domestic standards for medical devices.

The adequacy of your response dated November 23, 1010, cannot be determined at this time. You summarized revisions for your procedure, SQP20B - Data Analysis Procedure; however, a copy of the procedure showing its implementation was not included in the response.

15. Failure of the manufacturer to establish adequate procedures to ensure the dates and results of quality audits and re-audits are documented, as required by 21 CFR 820.22. For example, SQP17 Rev 1 "Internal Audit Procedure" dated July 14, 2003, does not define that the dates of quality audits and re-audits be documented.

You have not had the opportunity to provide a response since this violation was not listed on the FDA 483 as an observation.

16. Failure of the manufacturer to establish adequate procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example:

(a) Your firm's training record for quality auditors, SQP17-2 Rev 4 "**(b)(4)**," documents the training assessment of two individuals. Your firm was not able to demonstrate which individual completed the training assessment.
You have not had the opportunity to provide a response since this violation was not listed on the FDA 483 as an observation.

17. Failure to establish and maintain adequate procedures to ensure that Device History Records (DHR's) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR), as required by 21 CFR 820.184. For example:

(a) Three of three DHRs reviewed did not include or refer to the location of the dates of manufacture. For example, the DHRs for LVT 100 (S/Ns **(b)(4)** and **(b)(4)**), Dr. Camscope (lot no. **(b)(4)**), and Dr. Oppel (lot no. **(b)(4)**) do not include the dates manufacturing started; instead they provide the weeks of the months.

(b) Two of the three DHRs reviewed did not include complete acceptance records which demonstrate the device is manufactured in accordance with the DMR. For example,

i. The Dr. Camscope DHR did not include documentation of the cooling pan finished device acceptance activity.

ii. The Dr. Oppel DHR did not include documentation of the output registration test, which is a finished device acceptance activity.

(c) The three DHRs reviewed did not include device identification(s) and control number(s) used. For example, the DHRs did not document the label and labeling used for each production unit, lot, or batch.

(d) The three DHRs did not include the date the lots were released for distribution.

The adequacy of your response dated November 23, 2010, cannot be determined at this time. You summarized revisions for your procedure, SQP10 – Manufacturing Management Procedure, Product Standardization; however, a copy of the procedure showing implementation was not included in the response.

Our inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Significant violations include, but are not limited to, the following:

18. Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17. For example, you have no procedures for MDR.

The adequacy of your response dated November 23, 2010, cannot be determined at this time. You summarized revisions for your procedure, SQP14A - Corrective and Preventive Action Procedure, Section 7.2; however, a copy of the procedure showing its implementation was not included in the response.

A follow up inspection will be required to assure that corrections and/or corrective actions are adequate.

Given the serious nature of the violations of the Act, all devices manufactured by your firm are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA may take steps to refuse these products, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, you should provide a written response to this Warning Letter as described below and correct the violation(s) described in this letter. We will notify you if your response is adequate and we may need to re-inspect your facility to verify that the appropriate corrections have been made.

Also, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violation(s), from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to: Jason Brookbank, Acting Branch Chief, General Surgery Devices Branch, Division of Enforcement A, WO66-3520, at the address on this letterhead. Refer to CMS case # 164372 when replying. If you have any questions about the content of this letter please contact: Joseph Salyer at 301-796-5468 or fax at 301-847-8137.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

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