DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	12/01/2008 - 12/03/2008
	FEI NUMBER 1000525253

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Abraham W. Chames, Executive Vice President

FIRM NAME	STREET ADDRESS
Stat Medical Devices, Inc.	2056 Ne 153rd St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Miami, FL 33162-6020	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Adequate quality requirements that must be met by suppliers and contractors were not documented and implemented.

Firm's purchasing control is inadequate in that:

(A) Firm's pre-evaluation supplier audit of (b) (4) in (b) (4) did not include coverage of maintenance of tooling and did not document criteria that was covered.
(B) Firm's pre-evaluation supplier audit of (b) (4) in (b) (4) did not include documentation of criteria covered and no additional criteria was covered to cover operations for lancing devices before (b) (4) began this new product line.
(C) Supplier survey does not include process validation.

OBSERVATION 2

Procedures for verifying that design output meets design input were not implemented.

Firm has not assured that its 510(k) covering its Pen Needle device includes the silicone coating placed on the needle.

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	Richard K Vogel, Investigator Richard K. Vogel	12/03/2008

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OBSERVATION 3

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Firm failed to report 2 lancet failure to retract incidents during use of its Stat-Let Clinical Safety Lancets as referenced in Complaint 07-015 dated 11/22/2007.

OBSERVATION 4

The design verification results, including identification of the design, methods, the date, and the individual performing the verification, were not documented and filed in the design history file.

Documentation of biocompatibility test for silicone coating on its Pen needle is not available.

OBSERVATION 5

Process validation activities and results have not been fully documented.

(A) Firm lacks documentation of full (b) (4) sterilization validation study regarding its Pen Needle device as well as documentation of empty chamber studies, calibration of temperature sensors, and BI enumeration.
(B) Firm lacks documentation of full (b) (4) sterilization validation study regarding Stat-Let Auto Lancing device as well as dose map and product configuration documentation.

OBSERVATION 6

The results of design validation, including identification of the design, methods, the date, and the individual performing the validation, were not documented and filed in the design history file.

Documenation to demonstrate Pen Needle is compatible with most pen injectors in the market was not available.

OBSERVATION 7

Risk analysis is incomplete.

Risk analysis for Pen Needle does not include silicone coating.

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OBSERVATION 8

Records of complaint investigations do not include the results of the investigation.

(A) Firm failed to obtain adequate information to determine if serious injury occurred when it was reported in Complaint 07-015 dated 11/22/2007 that nurse was injured by Stat-Let lancet which did not retract after taking sample from a patient in that they did not determine if further medical intervention was taken to preclude serious injury.
(B) Firm did not document most likely root cause related to Complaint 07-015 dated 11/22/2007. It was verbally communicated that the root cause was failure of contract manufacturer in (b) (4) to do adequate maintenance of tooling causing flash which caused lancet failure to retract.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.

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