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	12/03/2008 - 12/05/2008
	FEI NUMBER 1000124817

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Alexander H. Barron, CEO

FIRM NAME	STREET ADDRESS
Marina Medical Instruments Inc.	955 Shotgun Rd
CITY, STATE, ZIP CODE, COUNTRY Sunrise, FL 33326-1964	TYPE ESTABLISHMENT INSPECTED 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 established, defined, documented, and implemented.

Firm's purchasing control procedure is inadequate in that:

(A) Firm's incoming inspections are not documented.
(B) Firm fails to assure that its contract manufacturers have adequate quality controls including but not limited to process validation for extrusion of tubes used in its Uterine Manipulator device, welding of cuffs used in its Uterine Manipulator device, and package seal validation.

OBSERVATION 2

Corrective and preventive actions have not been verified or validated to ensure that the action is effective and does not adversely affect the finished device.

Firm received communication from customer at hospital that no instructions for sterilization were provided with Marina Medical Miyazaki Lighted Retractor or Tenuculum Endoscopic Forceps which were repacked/relabeled by Marina Medical. Marina Medical provided sterilization instructions which recommended sterilization methods which are not recommended by OEM including (b) (4) sterilization. Customer (hospital) submitted Medwatch MW1034491 dated 1/18/2005 to FDA regarding Marina's inadequate and misleading sterilization instructions. Revised sterilization instructions were sent to the customer in 9/2005, but these sterilization instructions were still not according to OEM instructions for Miyasaki Lighted Retractor in that (b) (4) sterilization continued to be recommended. Firm only generated sterilization instructions according to OEM recommendation for Miyazaki device just prior to this

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present FDA inspection.

OBSERVATION 3

Process control procedures that describe any process controls necessary to ensure conformance to specifications were not established, defined, documented, and implemented.

Firm fails to provide Instructions For Use including any sterilizatiion/cleaning instructions for medical devices it repacks/relabels for which the OEM does provide such instructions.

OBSERVATION 4

Process validation activities and results have not been fully documented.

Firm lacks documentation of sterilization validation for its Uterine Manipulator except summary report of revalidation based on document review with no reference to biological indicators.

OBSERVATION 5

The design history file was not established or maintained.

Firm lacks design history files for medical devices for which it acts as repacker/relabeler or specification developer.

OBSERVATION 6

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

Firm's investigation of consumer complaints is inadequate in that:

(A) In follow-up to complaint in March 2007 regarding rupture of cuff of Uterine Manipulator inside a patient's uterus, there was no investigation documented by Marina Medical, there was no documentation of whether any medical intervention occurred during the incident, no reply letter was sent to complainant informing them of most likely root cause, and Marina Medical did not attempt to assure welding process of cuffs at contract manufacturer is adequately validated.
(B) In follow-up to complaint in March 2007 regarding split handle of Uterine Manipulator, there was no documentation of investigation done by Marina Medical, there was no documentation of whether medical intervention occurred during the incident, no reply letter was sent to complainant informing them of most likely root cause, and Marina Medical did not attempt to assure contract manufacturer has

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adequate purchasing control program covering the supplier who does molding of handles.
(C) In follow-up to complaints in March 2007 regarding tip of Uterine Manipulator found broken in the uterus and regarding tip of Uterine Manipulator which broke off and fell to the floor, there was photo returned by complainant of suspect device with broken tip, but it is not identified to which of the above tip complaints this photo relates, no reply letter was sent to the complainant informing them of the most likely root cause, and Marina Medical did not attempt to assure extrusion process used to make tube (tips) at contract manufacturer is adequately validated.

OBSERVATION 7

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 complaints dated March 2007 regarding tip of Uterine Manipulator found broken in the uterus and regarding tip of Uterine Manipulator which broke off and fell to the floor as MDR events.

OBSERVATION 8

Quality audits were not conducted at sufficient regular intervals, as prescribed by internal procedures to verify that the quality system is effective in fulfilling your quality system objectives.

Firm's internal audit procedure requires that internal audits be carried out on a yearly basis every April, however firm has not conducted an internal audit since April 19, 2005.

OBSERVATION 9

Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.

Management failed to establish personnel on site who have adequate knowledge of Quality System regulations. Firm established outside consultant to be in charge of quality assurance.

OBSERVATION 10

Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been implemented.

Firm has failed to follow its written complaint procedure for any complaints and firm has not differentiated between its return reports which meet definition of consumer complaints and those that do

not. For example: Returns from customers concerning defective light source and Webster Needle Holder with TC Insert that has broken off were not identified and investigated as complaints.

OBSERVATION 11

The procedures addressing documentation of corrective and preventive action activities were not complete and implemented.

(A) Firm has not generated any corrective actions according to its written CAPA procedure including corrective actions taken in regards to complaint referencing inaccurate sterilization instructions.
(B) Firm's CAPA procedure fails to require that all CAPA's are to be verified and/or validated as effective prior to implementation and that they do not adversely affect the finished device.

OBSERVATION 12

Procedures to control the design process of the device were not complete.

Firm's written Design Control procedure does not include reference to control of labeling and packaging and does not include how it is to adhere to design control sections (design planning, inputs, outputs, review, risk analysis, verification, validation, and changes).

OBSERVATION 13

Procedures for conducting quality audits were not complete.

Firm's Internal Audit procedure fails to document all internal audit criteria which should be covered during an internal audit including all applicable sectiions of the Quality System regulation, the MDR (Medical Device Reporting) regulation, and the Corrections & removals regulation.

OBSERVATION 14

Written MDR procedures have not been developed.

Firm's Reporting procedure fails to include MDR requirements.

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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.
Observation 9:	Promised to correct.	Observation 10:	Promised to correct.
Observation 11:	Promised to correct.	Observation 12:	Promised to correct.
Observation 13:	Promised to correct.	Observation 14:	Promised to correct.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Richard K Vogel, Investigator Richard K. Vogel	12/05/2008