Inspections, Compliance, Enforcement, and Criminal Investigations

Marina Medical Instruments Inc. 4/21/09

hhsbluebird **Department of Health and Human Services**

Public Health Service
Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

Certified Mail
Return Receipt Requested

WARNING LETTER

FLA-09-12

April 21, 2009

Alexander H. Barron, CEO
Marina Medical Instruments Inc.
955 Shotgun Rd
Sunrise, FL 33326-1964

Dear Mr. Barron:

During an inspection of your firm located in Sunrise, Florida on December 03, 2008,
through December 05, 2008, an investigator from the United States Food and Drug
Administration (FDA) determined that your firm manufactures products, including uterine manipulators that, under section 201(h) of the Federal Food, Drug, and Cosmetic
Act (the Act), 21 U.S.C. 321(h), 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** (CFR),
Part 820. We received your three responses dated December 8, 2008, December 15, 2008,
and January 29, 2009, concerning our investigator's observations noted on the Form FDA
483, List of Inspectional Observations that was issued to you. We address these responses below, in relation to each of the noted violations. These violations include, but
are not limited to, the following:

1. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). Specifically, your firm's purchasing control procedure is inadequate in that:

(A) Your firm's incoming inspections are not documented.

(B) Your firm failed 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.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded they are inadequate because your firm failed to
provide any documentation of incoming inspections and any documentation·

indicating
proper purchasing control. over your contractors.

2. Failure to validate with a high degree of assurance and approve according to established procedures a process, where the results of that process cannot be fully
verified by subsequent inspection and test, as required by 21 CFR 820.75(a).

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

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded they are inadequate because your firm does not
provide any documented evidence of an adequate sterilization validation for its uterine
manipulators.

3. Failure to record the dates and results of complaint investigations, as required by
21CFR 820.198(e)(6). Specifically, your firm's investigation of consumer complaints is inadequate in that:

(A)In follow-up to a complaint in March 2007 regarding rupture of cuff of Uterine Manipulator inside a patient's uterus, there was no investigation documented by Marina Medical.

(B) In follow-up to a complaint in March 2007 regarding the split handle of Uterine Manipulator, there was no documentation of investigation done by Marina Medical.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded they are inadequate because you failed to provide
any supporting documentation.

4. Failure to establish procedures for quality audits and conduct such audits to assure
that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.

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

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded they are inadequate because during the inspection
your firm indicated to the investigator that no internal audits had been completed since
April 19, 2005. Your internal audit procedure required an internal audit be done each
April, starting in April 2005.

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

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded they are only partially adequate because the
Internal Audit procedure has no approving signature.· Please provide a copy of the procedure with the approving signature.

5. Failure to adequately establish and maintain procedures for receiving, reviewing,
and evaluating complaints to ensure that all complaints are processed in a uniform
and timely manner, as required by 21 CFR 820.198(a)(1).

Specifically, your firm failed to follow its written complaint procedure for

complaints and has not differentiated between return reports which meet the 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.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and January 29, 2009, and have concluded they are inadequate because you failed to provide any supporting documentation which indicates you have implemented the actions mentioned in your response.

6. Failure to adequately maintain procedures for implementing corrective and preventive action, and failure to document all activities and results under this section. 21 CFR 820.100. Specifically,

(A) Your firm failed to take any corrective actions according to its written CAPA procedure including corrective actions taken in regards to a complaint referencing inaccurate sterilization instructions.

(B) Your firm's CAPA procedure failed to require that all CAPA's are to be verified and/or validated as effective and as not having an adverse effect on the finished device prior to implementation.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and January 29, 2009, and have concluded they are only partially adequate because the written CAPA procedure has no approving signature. Please provide a copy of the procedures with the approving signature.

7. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a).

Specifically, your firm's written Design Control procedure does not include

reference to the control of labeling and packaging and does not include how it will
comply with requirements for design and development planning, inputs, outputs,
review, risk analysis, verification, validation, and changes.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded they are only partially adequate because the
written Design Control procedure has no approving signature. Please provide a copy of
the procedures with the approving signature.

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 devices 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 deviations include, but are not limited to, the following:

1. Failure to develop, maintain, and implement written MDR procedures, as required
by 21 CFR 803.17.

For example, your firm has no written MDR procedures.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded that the responses are inadequate. The response
dated December 15, 2008, included an updated copy of Procedure Q13 (Postmarket
surveillance and Recall.) However, this procedure does not contain any written MDR
procedures, does not contain any reference to the MDR regulation and requirements, nor
does it contain information regarding how and where to submit MDR reports to the FDA.

2. Failure to clearly identify all MDR event files and maintain them to facilitate timely access, as required by 21 CFR 803.18.

For example, your firm received two user facility reports (#1100790000-20078001
and #1100790000-2007-8002) concerning incidents of Uterine Manipulator tip breakage. However, your firm did not include in your files any information as to why you considered these device malfunctions to not be MDR reportable. In addition, there is no information in regards to the complaint (#2007010) concerning the ruptured vaginal cuff of the Uterine Manipulator to indicate why your firm considered this device malfunction to not be MDR reportable.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded that the responses are inadequate. It appears that
your firm failed to submit MDR reports to the FDA. While we realize that the 21 CFR
803.18 charge was not explicitly mentioned in the FDA 483, your firm's overall responses did not adequately address this problem.

3. Failure to conduct an investigation of each event and evaluate the cause of the
event, as required by 21 CFR 803.50(b)(3).

For example, there is no information with the two user facility reports you received involving the complaints concerning the breaking of the tip of the Uterine Manipulator to indicate that your firm did an investigation into whether there were any clinical complications or any adverse clinical outcomes as a result
of these malfunctions. In addition, there is no information in regards to the complaint concerning the ruptured vaginal cuff of the Uterine Manipulator to indicate that your firm did an investigation into whether there were any clinical complications or any adverse clinical outcomes as a result of this malfunction.

We have reviewed your responses, dated December 8, 2008, December 15, 2008, and
January 29, 2009, and have concluded that the responses are inadequate. Your firm
failed to include any information regarding an investigation into whether there

were any
clinical complications or any adverse clinical outcomes as a result of the breaking of the
tip of the Uterine Manipulator. Also, your firm failed to provide supporting documentation to support the statement in Exhibit 14 (internal email correspondence)
claiming "No harm or damage to the patient," in regards to the incident involving the
ruptured cuff of the Uterine Manipulator. While we realize that the 21 CFR 50(b)(3) charge was not explicitly mentioned in the FDA 483, your firm's overall responses did
not adequately address this problem.

You should take prompt action to correct the violations addressed in this letter. Failure to
promptly correct these violations may result in regulatory action being initiated by the
Food and Drug Administration without further notice. These actions include, but are not
limited to, seizure, injunction, and/or civil money penalties. Also, 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 violations, 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.

Your response should be sent to: Winston R. Alejo, Compliance Officer, 555 Winderley
Place, Suite 200, Maitland, Florida, 32751. If you have any questions about the content
of this letter please contact: Mr. Alejo at (407) 475-4731.

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 these
violations, and take prompt actions to correct the violations and to bring your products
into compliance.

Sincerely,

/S/

Emma R. Singleton
Director, Florida District