DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715 Industry Information: www.fda.gov/oc/industry Industry Information: www.fda.gov/oc/industry	09/01/2016-09/02/2016
	FEI NUMBER 3008254127

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Brett M. Telford, Managing Director

FIRM NAME	STREET ADDRESS
Gynetech PTY LTD	122 Balmain Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Richmond, AU-VIC Australia 3121	Specification Developer

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) (WE) OBSERVED:

OBSERVATION 1

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.

Specifically, your firm failed to submit an MDR after becoming aware of the following complaints:
1. (b) (4), dated 06/23/2016, relating to a Manipulator PRO shaft bending during surgery making it difficult to manipulate the uterus and the metal distal tip of the balloon breaking through the balloon causing it to deflate and perforate through the uterus.
2. (b) (4), dated 03/08/2016, relating to a Manipulator having the broken sheath visible and a metal part being observed protruded during intra-operation.
3. (b) (4), dated 03/08/2016, relating to a Manipulator tip going through and through outside the uterus during a surgery. After the colpotomy and removal of the device from the uterus, the assistant noticed the metal tip punctured the balloon.
4. (b) (4), dated 12/10/2015, relating to the tip of a Manipulator Pro breaking when trying to extract the specimen.

OBSERVATION 2

Risk analysis was not performed.

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Specifically, your firm has no documented design risk analysis of the Manipulator Pro and Manipulator prior to (b) (4) although the 510(k) for the devices initially cleared in December 2014 and the design activities began in approximately (b) (4).

OBSERVATION 3

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Your firm has not ensured (b) (4) of the Manipulator and Manipulator (b) (4) these devices according to specified requirements. In addition, your firm's procedure (b) (4) Vendor Assurance And Qualification Procedure (b) (4) requires that high risk suppliers be audited on an annual basis. It was noted your firm has not established audit criteria.

OBSERVATION 4

Procedures for design transfer have not been adequately established.

Specifically, design transfers of the Manipulator Pro and Manipulator devices were not documented during the design projects that took place (b) (4). There is no documented evidence product specifications, applicable procedures, and specified requirements were transferred over to (b) (4) (b) (4) of the Manipulator Pro and Manipulator prior to them (b) (4) on your behalf except for the instructions for use, dated 06/01/2015, and immediate product labeling, dated 08/07/2014.

OBSERVATION 5

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

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A). Your firm's procedure (b) (4) Customer Complaints Procedure (b) (4) does not include a method to ensure complaints are processed in a uniform and timely manner. Your firm has not documented the requirement for complaints that (b) (4) receive to be communicated to you in a timely manner for complaint investigation. In addition, you have not ensured (b) (4) forwards (b) (4) investigations in a timely manner to your facility.

B). None of the (b) (4) complaint records reviewed include an adequate MDR determination in terms of assessing it for malfunctions that could likely contribute to or cause a death or serious injury if they were to recur.

C). Review of the (b) (4) complaint records revealed they were not always handled in a timely and uniform manner as evidenced by the following examples:
1. Complaint (b) (4) relating to a hair found in the syringe packaging of a Manipulator Pro was received on 08/06/2015 and closed on 07/07/2016.
2. Complaint (b) (4) relating to the LapScope Warmer not getting hot enough received on 08/28/2015 and closed on 07/07/2016.

OBSERVATION 6

Written MDR procedures have not been developed.

Specifically, your firm does not have a Medical Device Reporting procedure.

OBSERVATION 7

Design plans that describe or reference the design and development activities and define responsibility for implementation have not been adequately established.

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	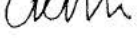	Ashley A. Mutawakkil	09/02/2016

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Specifically, your firm did not maintain adequate design plans for the Manipulator Pro and Manipulator device during the time of development (b) (4) to describe the development activities or define responsibilities of the different parties involved including (b) (4) (b) (4) utilized. In addition, your firm did not have established design plan procedures prior to (b) (4) even though your firm had conducted design activities for the Manipulator Pro and Manipulator device which initially received 510(k) clearance in December 2014.

OBSERVATION 8

Procedures for addressing incomplete, ambiguous, or conflicting design input requirements were not established.

Specifically,

A). Your firm's design procedure (b) (4) Design Control Procedure (b) (4) does not include a method for addressing incomplete, ambiguous, or conflicting design input requirements. In addition, your firm did not have established design input procedures (b) (4) even though your firm had conducted design activities for the Manipulator Pro and Manipulator device which initially received 510(k) clearance in December 2014.

B). Your firm did not maintain documented inputs during the design activities of the Manipulator and Manipulator Pro ((b) (4)) or evidence that design inputs were reviewed and approved by a designated individual. In addition, the retrospectively documented design input requirements were not adequately documented (i.e. lacking the consideration of minimum/maximum air pressure and volume).

OBSERVATION 9

Design outputs that are essential for the proper functioning of the device were not completely identified.

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Specifically, your firm has no documented evidence that design outputs were established and reviewed during the design activities conducted for the Manipulator Pro and Manipulator which took place (b) (4) (b) (4) In addition, you have no documented assessment showing the currently documented outputs allow an adequate evaluation of the conformance to design input requirements. Furthermore, your firm did not have established design output procedures (b) (4) even though your firm had conducted design activities for the Manipulator Pro and Manipulator device which initially received 510(k) clearance in December 2014.

OBSERVATION 10

Procedures for design change have not been adequately established.

Specifically, your firm did not formally document a design change conducted (b) (4) (b) (4) on the Manipulator Pro and Manipulator for a (b) (4) In addition, your firm did not establish a design change control procedure (b) (4)

OBSERVATION 11

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

Specifically,

A). The following design verification activities were not conducted using pre-determined acceptance criteria:
1. Post-Sterilization Performance Testing titled, "(b) (4) (b) (4)
2. Post-Sterilization Performance Testing titled, (b) (4)

B). (b) (4) Studies conducted for the Manipulator Pro under protocol, "(b) (4) (b) (4) " did not include a documented rationale for the conditions chosen and time points selected.

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C). Your firm has no documented evidence showing the test method used for performance testing, (b) (4) Performance Testing, was suitable for its intended use prior to utilizing it for design verification activities.

D). Your firm did not have established design verification procedures (b) (4) even though your firm had conducted design activities for the Manipulator Pro and Manipulator device which initially received 510(k) clearance in December 2014.

OBSERVATION 12

Procedures for design review have not been adequately established.

Specifically, design reviews were not documented for the Manipulator and Manipulator Pro at appropriate stages of the projects (b) (4) In addition, your firm did not have established design review procedures (b) (4) even though your firm had conducted design activities for the Manipulator Pro and Manipulator device which initially received 510(k) clearance in December 2014.

OBSERVATION 13

Procedures for management review have not been adequately established.

Specifically, your firm did not perform management reviews (b) (4) or have an established procedure (b) (4) even though your firm has been shipping class II devices to the U.S. since January 2014.

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OBSERVATION 14

Specifically, the internal audit procedure (b) (4) Internal and External Auditing Procedure, (b) (4) is inadequate in that it does not include a requirement to audit the elements of 21 CFR 820 and it does not discuss the requirement for auditors to be trained to 21 CFR 820. In addition, no internal audits were conducted (b) (4) (b) (4) even though your firm has been shipping class II devices to the U.S. since January 2014.

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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

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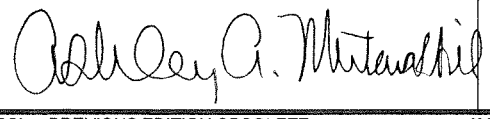
SEE REVERSE OF THIS PAGE		Ashley A. Mutawakkil	09/02/2016