DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	9/13/2017-9/15/2017
	FEI NUMBER 3012123033

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Luke W. Clauson , Chief Operating Officer

FIRM NAME	STREET ADDRESS
IanTech, Inc.	8748 Technology Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Reno, NV 89521	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

Procedures for control and distribution of finished devices have not been established.

Specifically,

During review of your quality records, I observed that (b) (4) units of your Micro Interventional Phaco Sectioning (MIPS) finished device (Lot#: 20161011-01P) were shipped from Reno, Nevada to (b) (4) (b) (4) prior to establishment of your Quality Management System.

The MIPS finished devices (Lot#: 20161011-01P) were manufactured and shipped prior to final release by your Quality Assurance (QA) department. According to documentation on the device Lot History Record, the finished devices (Lot#: 20161011-01P) were manufactured and shipped on 11/18/2016 while Quality Assurance release date for the lot is 11/28/2016.

However, documents, forms and procedures required for implementation of your Quality Management System were released on 12/23/2016 via DCO#: 001 and on 02/24/2017 via DCO#: 002. Training of personnel and complete implementation of your Quality Management System was finalized the 2nd quarter of 2017. Hence, you failed to establish a Quality System that was appropriate for you specific medical device while meeting requirements of the Medical Device Quality System Regulation; prior to shipment of your finished device in interstate commerce.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jude C Dike, Investigator	X Jude C Dike Investigator Signed By: 2000620664 Date Signed: 9/15/2017	9/15/2017

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FIRM NAME IanTech, Inc.	STREET ADDRESS 8748 Technology Way
CITY, STATE, ZIP CODE, COUNTRY Reno, NV 89521	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

OBSERVATION 2
Process validation activities have not been documented.

Specifically,

Your Controlled Environment Room (CER) Equipment ID: (b) (4) is documented as being an ISO Class 8 cleanroom used in the manufacture of your sterile finished device. However, on requesting for qualification records, you were unable to provide records documenting validation activities but you did provide validation result records.

Secondly, the CER ((b) (4)) qualification result records indicate that the cleanroom was qualified post manufacture of your finished device lot#: 20161011-01P.

OBSERVATION 3
Software used as part of the quality system has not been validated for its intended use according to an established protocol.

Specifically,

Your (b) (4) is a (b) (4) application used in your quality operation for document control as well as storing/sharing quality documents and records such as;

- Nonconforming material records
- Corrective and Preventive Action (CAPA) records
- Complaint records
- Some Training records
- Internal Audit records
- Document Change Order records

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- Quality Forms
- Standard Operating Procedures
- Manufacturing/Work Instructions

However, on requesting for the software validation records, you provided copies of a supplier evaluation record and the software brochure. These documents do not demonstrate that the software has been validated for it intended use according to an established protocol. Also when queried on the subject, your Quality Assurance Manager acknowledged that the software has not been validated.

Annotations to Observations

Observation 1: Under consideration
Observation 2: Reported corrected, not verified
Observation 3: Promised to correct

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