DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive Suite 205 Lenexa, KS 66212 (913) 495 - 5100 Industry Information: www.fda.gov/oc/industry	04/11-12/2018
	FEI NUMBER 1000117611

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Thomas J. Nares, Owner

FIRM NAME	STREET ADDRESS
TJN Manufacturing, Inc.	416 Perry Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Davenport, IA 52801	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) (WE) OBSERVED:

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
OBSERVATION 1

Quality system procedures and instructions have not been established.

Specifically,

Your firm has failed to establish the required quality system procedures necessary for the production of Medical Devices. Procedures and documentation for complaint handling, corrective and preventive actions, medical device reporting, and production and process controls have not been established and implemented.

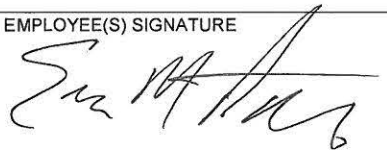
THIS IS A REPEAT OBSERVATION

OBSERVATION 2
Procedures for design change have not been established.

Specifically,

Your firm has failed to establish and implement procedures to ensure design changes to your class two medical device are documented and reviewed appropriately.

THIS IS A REPEAT OBSERVATION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		ERIC M. PAGETT, INVESTIGATOR	4/12/2018

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OBSERVATION 3
The ~~design history file~~ device history record was not established.

Specifically,

Your firm has failed to document a ~~design history file~~ device history record that shows that your class two medical device meets critical specifications and user requirements. No documentation relating to the manufacturing and release of each unit is maintained.

THIS IS A REPEAT OBSERVATION

OBSERVATION 4
Production processes were not controlled and monitored to ensure that a device conforms to its specifications. Specifically,

Your firm has failed to develop work instruction and final production check lists to ensure that all device are manufactured and produced per your firm specifications and meet all critical requirement. No work instructions, assembly verification forms, or final medical device acceptance documentation has been established.

THIS IS A REPEAT OBSERVATION

OBSERVATION 5
Procedures for corrective and preventive action have not been established.

Specifically,

Your firm has not established and implemented a corrective and preventive action procedure. No procedure for

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Eric M. Nares	Eric M. Nargett, Investigator	4/12/2018

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CITY, STATE AND ZIP CODE Davenport, IA 52801	TYPE OF ESTABLISHMENT INSPECTED Medical Device Manufacturer

how corrective actions resulting from complaints, deviation, non conformance will be documented and verified have ~~be~~ been established.

THIS IS A REPEAT OBSERVATION

OBSERVATION 6
Complaint files are not maintained.

Specifically,

You have not ~~document~~ documented and reviewed complaints relating to the class two medical device manufactured by your firm. Additionally, no complaint handling procedure has been established defining the requirements for documentation of medical device complaints.

THIS IS A REPEAT OBSERVATION

OBSERVATION 7
Written MDR procedures have not been implemented.

Specifically,

Your firm has failed to establish and implement procedures for the report of Medical Device Reportable events.
THIS IS A REPEAT OBSERVATION

NO ANNOTATIONS WERE REQUESTED

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Eric M. Haggett	Eric M. Haggett, Investigator	4/12/2018