DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/26/2018-3/1/2018
	FEI NUMBER 3000327445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ariel R. Dujovne, President and CEO

FIRM NAME	STREET ADDRESS
Pega Medical Inc.	1111 Chomedey (A-13) E
CITY, STATE, ZIP CODE, COUNTRY Laval, H7W 5J8	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

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically;

Process validation activities conducted by your firm did not encompass acceptance activities or documented evidence of manufacturing conditions representative of routine production activities intended to be validated. For example:

A. Validation Protocol "(b) (4) Validation of the (b) (4) ", approved on September, 2007, was intended to validate the (b) (4)

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(b) (4) . The objective of this validation was to determine the (b) (4) , and to evaluate the (b) (4) . The validation activity proposed to evaluate and compare (b) (4) , and the amount of (b) (4) . Procedure "(b) (4) (b) (4) ", executed during routine production for the (b) (4) process of (b) (4) requires a (b) (4) to determine the (b) (4) Nevertheless, the validation activity approved under the protocol before mentioned did not encompass acceptance criteria for (b) (4) , or related product testing, to ensure that the (b) (4) process was capable of ensuring that products complied with this required specification.

B. As per validation protocols "(b) (4) Validation of the (b) (4) Process for the (b) (4) , and "(b) (4) Validation of the (b) (4) Process for (b) (4) ", approved on 2007 and 2016 respectively, acceptance criteria for (b) (4) and (b) (4) processed in the same equipment did not include documented evidence that (b) (4) from (b) (4) were reduced to an acceptable level. The same (b) (4) is used to (b) (4) (b) (4) ; as well as (b) (4) . Nevertheless, no acceptance criteria was established, and no product testing was conducted for (b) (4) as part of the validation exercises, to demonstrate that (b) (4) were reduced to an acceptable level on (b) (4) and (b) (4) processed in the same equipment.

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C. As per procedure "(b) (4) ", executed during routine production for (b) (4) , specific volume of (b) (4) are required for the execution of the (b) (4) process. Nevertheless, validation protocols "(b) (4) Validation of the (b) (4) ", and "(b) (4) Validation of the (b) (4) " approved on 2007 and 2016 respectively, and intended to validate the (b) (4) process; did not contain documented evidence that these processing parameters were monitored and/or verified during the respective process validation activity. The DHR's for validation samples manufactured during validation did not contain documented evidence of these manufacturing parameters intended to be validated.

OBSERVATION 2

Procedures for corrective and preventive action have not been adequately established.

Specifically;

A. Corrective and Preventive Actions implemented by your firm did not encompass an evaluation of the validation of related manufacturing processes, after changes in respective manufacturing procedures were implemented.

CAPA (b) (4) was initiated on March, 2013, as a result of (b) (4) . The CAPA investigation determined that the root cause for the reported problem was that the procedure for inspection of the instrument, did not require to verify for (b) (4) . Corrective actions implemented included the revision of procedure "(b) (4) " and "(b) (4) Instrument Inspection Sheet-(b) (4) ". Nevertheless, the CAPA investigation did not

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encompass documented evidence that the change in the (b) (4) procedure impacted previous validation activities conducted for the (b) (4) process. As documented on validation protocol "(b) (4) Validation of the (b) (4) Process for (b) (4) ", approved on September, 2007, product testing conducted during the validation activity did not include acceptance criteria for (b) (4) . The manufacturing process was (b) (4) , under validation protocol "(b) (4) Validation of the (b) (4) Process for (b) (4) ".

B. The impact of confirmed product failures is not evaluated as part of CAPA investigations.

CAP (b) (4) as initiated on August, 2017 as a result of a reported complaint indicating that (b) (4) , the (b) (4) broke and the broken (b) (4) was (b) (4) . Corrective actions proposed under the CAPA included (b) (4) , and (b) (4) . Nevertheless, the CAPA investigation did not encompass documented evidence of evaluation of the related impact and risk associated to (b) (4) .

OBSERVATION 3
Procedures for acceptance activities have not been adequately established.

Specifically;

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Acceptance activities have not been adequately implemented. For example:

A. As per procedure "(b) (4) ", (b) (4) are to be (b) (4) . Nevertheless, there is no product testing conducted during routine manufacturing activities to demonstrate that products consistently meet the acceptable level of (b) (4) .

B. As per procedure "(b) (4) " testing of (b) (4) is conducted for (b) (4) (b) (4) . Nevertheless, no (b) (4) is tested for (b) (4) .

OBSERVATION 4

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

Specifically;

Production and process control procedures are not adequate in order to ensure that processing parameters are monitored and/or verified during routine production activities. For example:

Procedure "(b) (4) ", indicates that (b) (4) are required for (b) (4) . Nevertheless, (b) (4) (b) (4) DHR's reviewed during the inspection disclosed that these processing parameters are not

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documented and/or verified during routine production activities.

OBSERVATION 5

Procedures for changes to a procedure have not been adequately established.

Specifically;

Changes in product inspection instruction plans are not documented and/or evaluated on related production change documents. For example:

Inspection report (b) (4) for (b) (4) was approved on March 28, 2014 under a respective amendment sheet. Nevertheless, the changes described on the amendment sheet did not include (b) (4), a specification which was required to be inspected on the inspection report approved.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Reported corrected, not verified
Observation 3: Promised to correct
Observation 4: Promised to correct
Observation 5: Promised to correct

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