DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	5/3/2016-5/6/2016
	FEI NUMBER 1000117446

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Donnelle M. Fuerste , CEO

FIRM NAME	STREET ADDRESS
Metrix Co., dba The Metrix Company	4400 Chavenelle Rd
CITY, STATE, ZIP CODE, COUNTRY Dubuque, IA 52002-2655	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

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,

A. Per Corrective Action Report (CAR) 386, on 11/7/14 you determined that the compounding bags: 1000ml EVA (part number 66315), 2000ml EVA (part number 66325), 3000ml EVA (part number 66330) and 4000ml EVA (part number 66335) when used with the AutoComp6 XPS, the AutoComp6 XPS would not meet pumping accuracy requirements. Per your risk analysis report Y9016, O.1, page 12 inadequate performance of the unit was rated as (b) (4)). CAR# 386 documents that you contacted a hospital customer on 1/3/15 and advised them not to use the bags and you scrapped approximately (b) (4) of the listed compounding bags in stock. You did not submit an FDA MDR on this product malfunction within 30 days of becoming aware of the AutoComp6 XPS system would malfunction when using these compounding bags.

B. Per Corrective Action Report (CAR) 402 on 5/6/15 you determined that the compounding bags part numbers: 66725, 66325 and 66735 when used with the AutoComp6 XPS would not meet pumping accuracy requirements. Per your risk analysis report Y9016, O.1, page 12 inadequate performance of the unit was rated as (b) (4)). CAR# 402 documents you verified that users were

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confirmed not to have the affected product codes. You scrapped the listed compounding bags in stock. You did not submit an FDA MDR on this product malfunction within 30 days of becoming aware of the AutoComp6 XPS system would malfunction when using these compounding bags.

OBSERVATION 2

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically,

C. Per Corrective Action Report (CAR) 386, on 11/7/14 you determined that the compounding bags: 1000ml EVA (part number 66315), 2000ml EVA (part number 66325), 3000ml EVA (part number 66330) and 4000ml EVA (part number 66335) when used with the AutoComp6 XPS would not meet pumping accuracy requirements. Per your risk analysis report Y9016, O.1, page 12, inadequate performance of the unit was rated as (b) (4). CAR# 386 documents you scrapped approximately (b) (4) of the compounding bags with model number beginning with "663" (510k K030888), replaced this model with a new model number beginning with "667" (510k K030888) and updated the AutoComp6 XPS user manual. You did not report in writing of this correction and removal of medical device products to the FDA.

D. Per Corrective Action Report (CAR) 402 on 5/6/15 you determined that the compounding bags part numbers: 66725, 66725 and 66735 when used with the AutoComp6 XPS would not meet pumping accuracy requirements. Per your risk analysis report Y9016, O.1, page 12 inadequate performance of the unit was rated as (b) (4). CAR# 402 documents you verified that AutoComp6 XPS users were confirmed not to have the affected product codes. You scrapped approximately (b) (4) of the listed compounding bags in stock and decided to redesign theses bags (510k K030888). You did not report in writing of this correction and removal of medical device products to the FDA.

OBSERVATION 3

Procedures for design review have not been adequately established.

Specifically,

A. Engineering System Accuracy Validation Test (U1042VR) conducted on 8/29/14 noted that the new model AutoComp6 XPS serial number Beta9 failed the compounding accuracy specifications when using compounding bags model numbers 66305, 66325 and 66335. On or about 10/29/14 the first new model of the AutoComp6 XP was released to a customer for commercial use even though testing conducted the beta model failed testing in August.

The user manual included with the new unit listed compounding bag model numbers 66305, 66325 and 66335 were approved for use. There is no additional testing available documenting that either a beta unit or a production unit new model AutoComp6 XPS passed the accuracy validation test prior to commercial release.

B. Per Corrective Action Report (CAR) 402 an Engineering System Accuracy Validation Test was conducted on or about 5/6/15 to validate the AutoComp6 XPS using the redesigned “667” series compounding bags. Model codes 66725, 66730 and 66735 compounding bags failed to meet the compounding accuracy specifications. This series of bags (667) were specifically redesigned to meet the compounding accuracy specifications requirement.

Approximately one month prior to the validation test, between 4/3/15 and 4/30/15, the following quantities of the new “667” series bags were sold:

- Product code 66725 (b) (4) cases or approximately (b) (4) compounding bags of lot number 66725-A0512
- Product code 66735 (b) (4) cases or approximately (b) (4) compounding bags of lot number 66735-A0514
- Product code 66730 (b) (4) cases or approximately (b) (4) compounding bags of lot number 66730-

A0513

There is no additional testing available that documents theses first production compounding bags of the new model series “667” passed the accuracy validation test with the AutoComp6 XPS prior to commercial release in April 2015.

OBSERVATION 4
Risk analysis is incomplete.

Specifically,

E. You determined that the AutoComp6 XPS unit failed validation for not meeting compounding accuracy specifications when used with specific models of the compounding bags in November 2014 and May of 2015. However you did not update the risk analysis report Y9016 for the AutoComp6 XPS and accessories to include:
    a. Diameter of the compounding bag tubing
    b. Health risk when pump exceeds compounding accuracy specifications

F. The AutoComp6 XP uses the same compounding bags as the AutoComp6 XPS and has the same compounding accuracy specifications. Although by June 1, 2015, you had sold and were providing service for (b) (4) AutoComp6 XP compared to the (b) (4) AutoComp6 XPS. You did not update the risk analysis of the AutoComp6 XP to determine if:
    a. The “663” series of bags would cause theAutoComp6 XP to fail to meet stated compounding accuracy same as the similar AutoComp6 XPS.
    b. The “667” series of bags released in April 2015 would cause theAutoComp6 XP to fail to meet stated compounding accuracy same as the similar AutoComp6 XPS,
    c. The health risk impact to patient health when pump fails to meet compounding specifications

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G. Risk of using the AutoComp6 XP and XPS units for compounding of drugs is not identified in the risk analysis.

OBSERVATION 5

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

Specifically,

H. The test method used in the validation protocol for the AutoComp6 XPS as described in documents U1129VR and U1042VY has not been validated. There is no SOP or other procedure documenting the test method. There is no documentation available that demonstrates that this method has the Repeatability, Accuracy and Precision to be used determine the AutoComp6 XPS compounding accuracy specifications. This validation test uses (b) (4). The test method states that the (b) (4) However the method does not appear to compensate for changes in (b) (4).

I. There is no documentation showing that this is an accurate validation for the fluids which the hospital will be compounding. The test uses (b) (4). The test method does not document how using (b) (4) for the Parenterals which are the intended liquids to be compounded using the AutoComp6 XPS. For example, the validation does not state how (b) (4) as the Parenterals.

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OBSERVATION 6

Service reports were not analyzed following appropriate statistical methods.

Specifically, you stated that the service reports for the AutoComp6 XP are not analyzed following statistical methods and are not included into the complaint system. You stated service reports are not included as an input into the your CAR (Corrective Action Reporting) system.

OBSERVATION 7

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

Specifically, per Corrective Action Standard Operating Procedure (SOP) document 4.14.01 procedure 6.3.2.2.1 "***The (b) (4) Method is used for determining the root cause. At Least (b) (4) questions must be completed***". There was no root cause analysis accomplished for Corrective Action Report (CAR) 386 or 402.

OBSERVATION 8

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically, a (b) (4)

Annotations to Observations

Observation 1: Under consideration
Observation 2: Under consideration

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Observation 3: Under consideration
Observation 4: Under consideration
Observation 5: Under consideration
Observation 6: Under consideration
Observation 7: Under consideration
Observation 8: Under consideration

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