DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 Industry Information: www.fda.gov/oc/industry	03/04/2020 - 03/11/2020
	FEI NUMBER 3015826069

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kevin J. McClung, D.Ph. / Owner and PIC

FIRM NAME	STREET ADDRESS
Vital Care of Dickson, LLC.	758 Hwy 46 South, Suite 100
CITY, STATE AND ZIP CODE Dickson, TN 37055	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) WE) OBSERVED:

OBSERVATION 1

Compounding with APIs that have not been verified to assure that they do not contribute endotoxin contamination that may be objectionable given the product's intended use.

Specifically, the Certificate of Analysis for the APIs that the firm uses do not document if endotoxin tests have been performed and the firm has not performed any endotoxin testing on APIs or finished sterile drug products which are for intrathecal administration.

OBSERVATION 2

Failure to conduct media fill studies that closely simulate aseptic processing operations under the worst-case, most-challenging and stressful conditions.

Specifically, the firm compounds TPN products which involves several timely aseptic manipulation steps. The current media fills are performed only with a few aseptic manipulation steps.

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	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Marvin D. Jones -S Digitally signed by Marvin D. Jones -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1307135803, cn=Marvin D. Jones -S Date: 2020.03.11 13:31:13 -05'00'	Marvin D. Jones - Investigator	03/11/2020

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OBSERVATION 3
Pressure differentials are not monitored in areas where aseptic processing occurs.

Specifically,

A) Pressure differentials between areas with different air classifications (ISO 6 cleanroom and ISO 7 anteroom) are not routinely monitored/documented prior or during sterile drug production. A review of the firm's compounding records noted that the firm does not routinely document pressure differentials.

B) Pressure differentials are measured with wall-mounted manometers which are not visible from within the cleanroom. For example, I observed the firm performing sterile compounding on 03/05/2020 and I observed that the differential pressure gauge readings between the cleanroom and the anteroom were not within acceptable ranges. The cleanroom reading was .015 and the anteroom reading was .025. The firm was processing patient specific sterile drug products which included Morphine Sulfate 7.5 mg/ml and Morphine Sulfate 12 mg/ml both with a BUD of 03/05/2020 and for intrathecal administration.

OBSERVATION 4
Procedures designed to prevent insanitary conditions are not established or followed.

Specifically, on 03/05/2020, I observed non-sealed air gaps around the light fixtures in the firm's anteroom and cleanroom. The firm was processing patient specific sterile drug products which included Morphine Sulfate 7.5 mg/ml and Morphine Sulfate 12 mg/ml both with a BUD of 03/05/2020 and for intrathecal administration.

OBSERVATION 5
Disinfecting agents used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, the disinfectant ((b) (4)) used by the firm is non-sterile.

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