UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60604

DATE: NOV 2 1 2018

SUBJECT: CLEAN AIR ACT INSPECTION REPORT
Viant Medical, Grand Rapids, Michigan

FROM: Jason Schenandoah, Environmental Engineer
AECAB (IL/IN)

THRU: Nathan Frank, Section Chief
AECAB (IL/IN)

TO: File

BASIC INFORMATION

Facility Name: Viant Medical

Facility Location: 620 Watson Street SW, Grand Rapids, Michigan

Date of Inspection: October 12, 2018

EPA Inspector(s):
1. Jason Schenandoah, Environmental Engineer
2. Marie St. Peter, Environmental Engineer

Other Attendees
1. April Lazzaro, Senior Environmental Quality Analyst, Michigan Department of Environmental Quality (MDEQ)
2. Jorge Acevedo, Senior Environmental Engineer, MDEQ
3. Caryn E. Owens, Environmental Engineer, MDEQ
4. Bryan Curry, Senior Director Quality Assurance and Regulatory Affairs, Viant Medical
5. Tom Campbell, Sterilization Engineer, Viant Medical
6. Matthew G. Kwiatkowski, Professional Engineer, Environmental Resources Management

Contact Email Address: bryan.curry@viantmedical.com

Purpose of Inspection: Assist MDEQ inspection with technical expertise

Facility Type: Medical equipment sterilization facility

Arrival Time: 11:17 am
Departure Time: 2:00 pm

Inspection Type:
☐ Unannounced Inspection
☒ Announced Inspection

OPENING CONFERENCE

☒ Credentials Presented
☒ CBI warning to facility provided

The following information was obtained verbally from Viant personnel unless otherwise noted.

Company Ownership: The company was rebranded as Viant in summer 2018 from Medplast, LLC.

Process Description: Medical equipment in cardboard boxes is received on racks and are placed into a preconditioning room to be conditioned at the required temperature and humidity. Preconditioned medical equipment racks are then placed into one of five fumigating chambers in a batch process. Ethylene oxide is introduced into the chambers for a predetermined set of time to sterilize the medical equipment. After fumigation with ethylene oxide is complete, cycles of nitrogen, air, and vacuum are subjected to the chamber in order to evacuate ethylene oxide from the chamber. The emissions collected by the vacuum pump that pulls from the fumigation chambers are controlled by a relatively small scrubber before being vented to a larger scrubber. After the chambers are evacuated, the racks are pulled from the chambers and brought to one of five aeration cells to aerate residual ethylene oxide from the equipment. All emissions from the fumigation chambers, other than those pulled on the vacuum pump, exhaust from the small scrubber and emissions from the aeration cells are vented to the large scrubber for control.

Staff Interview: Certain batches of medical equipment are delicate and require a lighter vacuum pressure in the fumigation chamber. Multiple lighter vacuum sessions are needed to remove ethylene oxide, but it is less successful at removing ethylene oxide than deeper vacuum sessions. Ethylene oxide levels throughout the facility are measured by a gas chromatographer; 8 sample locations throughout the facility draw air to the gas chromatographer. Facility personnel stated that elevated levels of ethylene oxide are measured when racks are transported from fumigation chambers to aeration cells. Fugitive emissions are calculated by multiplying the average ethylene oxide concentration in the facility by the flow rate of the ventilation exhaust. Facility air is also monitored by a catalytic bead sensor; the catalytic bead sensor controls alarms at the facility. Hoods above the doors of the fumigation chambers vent to the atmosphere.

TOUR INFORMATION

EPA toured the facility: Yes

Data Collected and Observations: As the fumigation chamber door was opened, the back vent in the chamber kicked on. The back vent pulls gases from the chamber to the large scrubber. All racks are pulled out of the fumigations chamber when the cycle is completed as a forklift grabs one rack at a time to transport to the aeration cells. Some racks sit outside of the fumigation chamber for a time before the forklift picks them up to bring them to the aeration cells.

Photos and/or Videos: were not taken during the inspection.

Field Measurements: were taken during this inspection.
All field measurements are described in Appendix A.

Compliance Assistance: EPA noted the following points of improvement that Viant could undertake at the Facility:

- Coated cardboard seems to hold residual ethylene oxide; packaging changes could help;
- Racks of equipment could be left in the fumigation chamber until the forklift is ready to pick up the rack;
- Stack the boxes on the racks so there is less space between the boxes where residual ethylene oxide may stay.

SIGNATURES

Report Author: _____ Date: 11/21/2018

Section Chief: _____ Date: 11/21/18

Facility Name: *Facility Name*
Facility Location: *Facility Address*
Date of Inspection: *Select date by clicking on the arrow*

APPENDICES AND ATTACHMENTS

Appendix A: Field Measurement Data

Facility Name: Viant Medical
Facility Location: 620 Watson St. SW Grand Rapids, MI
Date of Inspection: October 12, 2018

APPENDIX A: FIELD MEASUREMENT DATA

- EPA operated Flame Ionization Detectors on two Toxic Vapor Analyzer (TVA) 2020s at the facility to detect volatile organic compounds (VOCs). EPA identification numbers for the two TVA 2020s are A56575 and A56584.
- Calibration measurements are listed in the table below:

Concentration (ppm)	A56575 reading (ppm)	A56584 reading (ppm)
500	494	494
2000	1994	1974
10000	10200	9986

- All measurements took place during the inspection between 11:17 am and 1:35 pm on October 12, 2018.
- All measurements were taken using EPA Method 21 procedure.
- EPA made measurements of a batch of equipment as it exited a fumigation chamber, the batch was a normal batch that utilized deep vacuum to evacuate ethylene oxide from the chamber before opening the chamber door.
- A VOC concentration reading of 3 parts per million (ppm) was detected at the interface of the door with the fumigation chamber at the moment the door was opened.
- Measurements were taken around the racks as they sat awaiting transport to the aeration cells. VOC concentration levels from 5 to 30 ppm were detected in crevasses between boxes on the racks.
- A measurement of 2 ppm was detected while following a rack being transported to the aeration cells.
- Measurements were taken around racks that had been removed from an aeration cell. It was noted that residual VOCs could be measured around the edge of coated corrugated boxes. Measurements were approximately 10 ppm.
- A measurement of approximately 0.5 ppm was taken at an exhaust vent from outside the building, Viant personnel stated that it was exhausting from the room that the vacuum pump was located in.
- EPA method 21 was conducted on components throughout the facility that were in service, no measurements above background were taken.