DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

September 16, 2009

Mr. James I. Lee, Executive Vice President/COO (Chief Operating Officer)
Vortran Medical Technology 1 Inc.
21 Golden Land Ct.
Sacramento, CA 95834-2426

Reference: FEI # 1000307109

Dear Mr. Lee:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your facility located at 21 Golden Land Ct., Sacramento, CA on February 24-26, 2009 by the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is closed, under 21 C.F.R. 20.64(d) (3), it will release a copy of the EIR to the inspected establishment.

The agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there are any questions about the released information you may contact Investigators Michael L. Tripp at 916-930-3674 x118 or Asher P. Parikh at 916-930-3674 x100.

Sincerely

Barbara J. Cassens, District Director
San Francisco, District Office

SUMMARY

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This QSIT (Quality System Inspection Technique) Level II Baseline inspection of Vortran Medical Technologies 1, Inc., a Class II medical device manufacturer was initiated pursuant to San FY 09 2nd Quarter Work Plans, [redacted], and includes coverage under CP 7382.845, Inspections of Medical Device Manufacturers.

The last U.S. Food and Drug Administration inspection was conducted in 1998 by CDRH (Center for Radiological Health), and was classified as non-violative. The report for that inspection was unavailable for review.

This inspection was conducted by Ashar P. Parikh and me, Michelle L. Tripp.

The section under the heading "History" was written by Ashar P. Parikh.

The remainder of the report was written by me.

In this report the term "we" refers to Investigator Ashar P. Parikh, and me.

The duration of the inspection was three days.

On 2/24/09, we presented our credentials and issued a Form FDA 482, Notice of Inspection to Mr. James I. Lee, Executive Vice President/COO (Chief Operating Officer), and the most responsible individual at the facility, on a day to day basis.

This inspection includes coverage of the following QSIT Sub-systems:

1. Management Controls
2. Corrective and Preventive Action Controls
3. Design Controls
4. Production and Processing Controls

This inspection found no objectionable conditions and no Form FDA 483, Inspectional Observations was issued.

No refusals were encountered.

No samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Vortran Medical Technology 1 Inc
Location:	21 Golden Land Ct Sacramento, CA 95834-2426
Phone:	800-434-4034
FAX:	916-648-9751
Mailing address:	21 Golden Land Ct Sacramento, CA 95834-2426
Dates of inspection:	2/24/2009, 2/25/2009, 2/26/2009
Days in the facility:	3
Participants:	Michelle L. Tripp, Investigator Ashar P. Parikh, Investigator

HISTORY

Vortran Medical Technologies, Inc. was incorporated in California in 1983. In 1998, the firm merged with West Med of Tucson, AZ, which bought out all Vortran products manufactured prior to 1998. The merger with West Med resulted in the corporate name being changed to Vortran Medical Technologies 1, Inc.

The firm has relocated and has been at its current location since 2007.

The firm's corporate office is located at 3941 J St. Ste. 354, Sacramento, CA 95814.

Correspondence related to this inspection should be addressed to Dr. Gordon A. Wong, Chairman of the Board, President & C.E.O. (Corporate Executive Officer), and the most responsible individual at the firm. Mr. Wong's office is located at the corporate address.

The firm's hours of operation are Monday through Friday, 9 A.M. to 5 P.M.

There are 12 employees.

INTERSTATE COMMERCE/JURISDICTION

Vortran Medical Technologies 1, Inc. is a specification developer and manufacturer of prescription single- patient-use disposable automatic respiratory products. The firm manufactures a non-cycling monitor, also a Class II medical device, which can be purchased separately and is to be used exclusively with the firm's respirators. (See Exhibit 1, product brochures, along with label inserts, for a full line of the firm's finished products)

According to Mr. Lee, the firm distributes approximately 80 to 90% of its finished product into interstate commerce.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

In addition to Mr. Lee, we met the following individuals:

Ray Saied, Vice President of Engineering and Quality Assurance
Jody McCarthy, Vice President of Sales and Marketing
Teresa M. Cha, Director of Manufacturing
Glen Thomson, Vice President of Operations

Each of these individuals assisted us and/or provided us with information relevant to his or her respective areas of responsibility.

See Exhibit 2, Vortran Medical Technologies 1, Inc. Organizational Chart, for the firm's corporate structure.

MANUFACTURING/DESIGN OPERATIONS

On the first day of the inspection, we were escorted by Mr. Lee, Mr. Saied, and Ms. Cha, and provided access to the production assembly room, shipping, receiving, storage warehouse, and the quality control laboratory. (See Exhibit 3, Vortran Medical Technology 1, Floor Plan.)

This inspection covered all four of the QSIT Sub systems:

MANAGEMENT CONTROLS

During the inspection, we reviewed the firm's quality policy, internal audit procedures, management review procedures, and the internal audit schedule.

These documents appeared to be in compliance with United States Food and Drug Administration (U.S.F.D.A.) Quality System Regulations.

DESIGN CONTROLS

During the inspection, we reviewed the design history file, including the software validation, and portions of the 510(k) submittal for the firm's VAR™ Monitor. We selected this design as it is the firm's most recent design project.

These documents appeared to be in compliance with the U.S. F.D.A. Quality System Regulations.

CORRECTIVE AND PREVENTIVE ACTION CONTROLS

During the inspection, we reviewed the firm's CAPA (Corrective and Preventive Action) procedures, complaint handling procedures, and MDR (Medical Device Reporting) procedures.

These documents appeared to be in compliance with U.S. F.D.A Quality System Regulations.

Additionally, we reviewed 20 customer complaints and 10 CAPA's.

Each of the CAPA's and customer complaints we reviewed were handled and/or investigated appropriately.

The firm has had no MDR's, corrections or removals.

PRODUCTION AND PROCESSING CONTROLS

For this portion of the inspection our review included, but was not limited to the following documents: SOP (Standard Operating Procedure) 202 rev C, Component Acceptance and Receiving Inspection, SOP 218 rev H, Identification and Traceability, SOP 216, rev E, Ordering, Shipping, Backorders, Samples, vendor audit procedures, packaging and labeling SOP's, and the device history files for the VAR™ Plus 4010, lots numbered 860,861, and 863.

These documents appeared to be in compliance with the U.S. F.D.A. Quality System Regulations.

As part of the inspection, we asked the firm to demonstrate the use of one piece of measuring equipment, and one piece of production equipment.

Mr. Lee demonstrated the use of the cascade impactor, which is used to measure particle size of an aerosol to produce a predetermined flow rate.

Ms. Cha demonstrated the use of the Branson™ 900 series ultrasonic welder, which is used for welding the seams of the plastic modulators used as components of the firm's respirators.

Calibration and monitoring records for the cascade impactor were maintained adequately, as were the maintenance records for the ultrasonic welder, which did not require calibration.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No objectionable conditions were observed.

REFUSALS

No refusals were encountered.

EXHIBITS COLLECTED

1. Vortran Medical Technology 1, Inc. Product Brochures
2. Vortran Medical Technology 1, Inc. Organizational Chart
3. Vortran Medical Technology 1, Inc. Floor Plan

ATTACHMENTS

1. Form FDA 482, Notice of Inspection

Michelle L. Tripp, Investigator

Ashar P. Parikh, Investigator