Unetixs Vascular Inc. 4/25/17

U.S. FOOD & DRUG ADMINISTRATION

New England District Office
(NWE-DO)
One Montvale Avenue, 4th floor
Stoneham, MA 02180
Phone 781.587.7500

WARNING LETTER
CMS # 523178

UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

April 25, 2017

Neeraj Jha, CEO
Unetixs Vascular Inc.
125 Commerce Park Road
North Kingstown, RI 02852-8420

Dear Mr. Jha:

The United States Food and Drug Administration (FDA) conducted an inspection of your firm's medical device operations at 125 Commerce Park Road, North Kingstown,

RI, from March 6 through 29, 2017. During the inspection, an FDA investigator determined that your firm is a manufacturer of vascular diagnostic ultrasound systems, such as the MultiLab Series II. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

Your significant violations are as follows:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example:

- During the inspection, we observed that 1453 complaints, received from January 2015 to February 2017 were still open and have not yet been investigated. Your complaint procedure, QSP 12 – Servicing Activities, requires an analysis of all your complaints.

2. Failure to review, evaluate and investigate any complaint involving the possible failure of a device, labeling or packaging to meet any of its specification, as required by 21 CFR 820.198(c). For example:

- 17 out 17 complaint records reviewed during the inspection; B4595; B4515; B5024; B4185; B4607; B4602; B5046; B5103; B5164; B4892; B4765; B4605; B4742; B4821; B4687; B3027; and B4312, revealed that your firm failed to document the nature and details of the complaint, including whether a patient was harmed.

3. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). For example:

- Your firm has not analyzed any of your 1453 complaints received since 2015 to identify any existing or potential causes of nonconforming product, or other quality problems.

4. Failure to document corrective and preventive action activities, as required by 21 CFR 820.100(b). For example:

- Your firm opened 12 corrective action and / or preventive action reports since 2015. Seven of these reports were reviewed during the inspection; PA1044,

PA1045, CA1349, CA1348, CA1350, CA1353, and CA1351. All seven reports were missing required documentation, such as an analysis of processes or work operations to identify potential causes of quality problems.

5. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure, as required by 21 CFR 820.70(b). Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. For example:

- During the inspection four out of six Engineering Change Records (ECR's) were reviewed; ECR0104; ECR0087; ECR0112; and ECR0063. These records did not include documentation of required verification activities.

6. Failure to establish and maintain procedures for acceptance activities that include inspections, tests, or other verification activities, as required by 21 CFR 820.80(a). For example, a review of acceptance testing performed at your facility revealed the following inconsistencies:

- Material inspection reports for three components were reviewed during the inspection: **(b)(4)**. These reports did not include required functional/ mechanical fit, dimensional and visual inspection test results. These components were accepted despite the missing information.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Please send your reply to the Food and Drug Administration, Attention: Karen N. Archdeacon, One Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issues in this letter, please contact Ms. Archdeacon at 781-587-7491 or at karen.archdeacon@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Joseph Matrisciano, Jr.
District Director
New England District Office

Cc:
Mr. Vinod Ramani
CEO and Chairman
Opto Circuits (India)
Limited Unit III, Shed # 15, sdf-iBuilding,
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More in 2017

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Contact FDA