U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Inovo, Inc 2/19/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

WARNING LETTER
FLA-15-14
February 19, 2015

Richard J. Kocinski
President
Inovo, Inc
401 Leonard Blvd North
Lehigh Acres, FL 33971

Dear Mr. Kocinski:

During an inspection of your firm located in Lehigh Acres on November 17-19, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the AccuPulse Model 6505 oxygen conserver, Bonsai Velocity oxygen conserver, Evolution oxygen conserver, Evolution with Motion oxygen conserver, SmartDose oxygen conserver, Smart Does Mini oxygen conserver, Oxymizer Disposable oxygen conservers, and oxygen Regulators. 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 are intended to affect the structure or 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.

We received responses from Michael T. Dildine, Quality Assurance Director dated November 26, 2014 and January 12, 2015 concerning our investigator's observations noted on the Form FDA 483 (FDA 483), Inspectional Observations, which was issued to you on November 19, 2014. We address these responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to adequately establish and maintain procedures for implementing corrective and preventive actions (CAPA), as required by 21 CFR 820.100(a). Specifically,

a. your firm has not determined the most likely underlying cause or initiated adequate corrective actions in relation to complaints of Evolution, SmartDose and Part 6505 Pneumatic Qxygen Conservers pulse malfunction issues which could cause the devices to fail to provide patients with specified oxygen amounts and result in hypoxemia;

b. your firm's CAPA Process, IQP-014 Rev B dated 09/26/14, does not require that each CAPA be verified or validated and that they do not adversely affect the finished device; and

c. your firm documented that an incoming shipment of inhalation switches failed sensitivity testing in Nonconforming Material Report IFC-047 # 17043 dated 08/16/14. Your supplier reported their manual process caused too much variation and agreed to institute the use of a pneumatic press. Your firm failed to document adequate verification/validation of this action's effectiveness and to determine that it would not adversely affect the finished device.

We reviewed your firm's responses and conclude that they are not adequate.

a) Although your review of the complaint data appears to indicate the need for further failure investigation, your response does not include supporting documentation of the timely and possibly adequate corrective and preventive action.

b) It appears you have adequately amended your procedure; however, supporting documentation of the implementation of this procedure was not included.

c) Your response did not include supporting evidence of the initiation of CAPA # 21176.

2. Failure to establish procedures to adequately control environmental conditions where environmental conditions could reasonably be expected to have an adverse effect on product quality as required by CFR 820.70(c). For example, your firm has no written justification for the absence of electrostatic discharge reduction procedure.

We reviewed your firm's responses and conclude that they are not adequate. It does not appear that you have initiated any electrostatic discharge operations and have only drafted written documents. Your responses includes a work environment procedure and a work instruction procedure that do not explicitly reference each other. Additionally, your plans do not include provisions for the training of the employees on the work instructions yet to be created for your three internal manufacturing instructions.

3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. Specifically, your supplier procedure, Supplier Management: Selection, Authorization, & Maintenance IQP 021 Rev D dated 12/14/13, does not require the supplier's provision of written evidence of critical controls for manual processes including process validation for anodization, pick & place, wave soldering equipment, or personal training.

We reviewed your firm's responses and conclude that they are not adequate. It does not appear that your firm has outlined an adequate timeline or plan of the possible requalification of your suppliers or the actual implementation of these procedures.

4. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). Specifically,

a. Your software development /validation:

i. does not include written procedures covering the development/validation of the software used in your devices;

ii. documentation for your Evolution Oxygen Conserver device does not include structural testing at the code level (use of static code checkers, independent code review, etc); and

iii. software product testing procedure, Database/Software Controls IQP 030 Rev A dated 10/20/08, does not require structural testing and does not include provisions for the adequate description of regression testing.

b. Your risk analysis procedure, Risk/Hazard Analysis for your OM-900 Series Oxygen Conserving Device SP-206 Rev D dated 02/27/13 does not include:

i. risks/hazards related to the corrosion and mitigation actions such as anodization; and
ii. the causes of the risk of inadequate pulsing such as defective inhalation switches, piezo valves and printed circuit boards and their respective mitigation actions.

c. The available clinical studies documentation for the following Evolution Oxygen Conservers:

i. did not include the written protocol or the patient's baseline saturation levels for the 900M model; and
ii. did not include the baseline saturation levels or the device settings for the patients.

We reviewed your firm's responses and conclude that they are not fully adequate.

a) The revisions to your software procedures and the initiation of the added testing requirements do not appear to timely relative to the criticality of this deficiency.

b) Although you have included the cited cause and failure modes, a comprehensive review may help to identify further deficiencies.

c) The information provided for this citation appears to be adequate.

5. Failure to maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, your complaint handling procedure, Post Market/Analysis/ Vigilance Process IQP-008 Rev B dated 04/29/14 does not:

a. ensure that records of complaint investigations, when necessary, include the required information.

For example, your firm failed to document the following elements in 10 complaints associated with your OM-900 Evolution (6), SmartDose (2) and Model 6505/Accupulse (2) devices:

i. adequate details or nature of the complaint including the setting in which the malfunction occurred;
ii. resultant patient adverse effects; and
iii. whether further medical intervention was require enquired.

b. define timeliness of complaint investigations until after a subject device is returned to your firm.

The adequacy of your firm's responses cannot be determined at this time. Your responses did not include supporting documentation that the referenced procedure has been implemented.

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 (including any systemic corrective actions) 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 U.S. Food and Drug Administration, Attention: Andrea H. Norwood, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, FL 32751. If you have any

questions regarding any issues in this letter, please contact Ms. Norwood by telephone at (407) 475-4724.

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/
Susan M. Turcovski
Director, Florida District

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