

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421  
Telephone: 425-486-8788  
FAX: 425-483-4760**

December 13, 2007

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 08-05

Mr. Mario V. Sorci, President  
G. Dundas Company, Inc.  
24301 Roberts Drive  
Black Diamond, Washington 98010

**WARNING LETTER**

Dear Mr. Sorci:

During an inspection of your firm located in Black Diamond, Washington, conducted on June 15 and 18, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the APL Valve and Gas-Scavengers (Passive and Active) which are used in conjunction with anesthesiology machines. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices that 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. We received a response from you dated September 14, 2007, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to you on June 15, 2007, but we could not conduct a review as no documentation was provided.

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 (cGMP) requirements of the

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Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. These violations include, but are not limited to, the following:

1. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. Your procedure for conducting quality audits is deficient in that it only covers tools and test equipment and inspection requirements. Your last audit report dated June 1, 2007, only covered inspection of tools and test equipment.
2. Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). You could not provide design control change procedures during the inspection even though you have made changes to two of your devices. You changed the Passive Gas-Scavenger from Model 1920-5590 to 14600/14600-E, and the Active Gas-Scavenger from Model 1920 to 1925.
3. Failure to document acceptance activities, as required by 21 CFR 820.80(e). You perform finished product testing on every Active Gas-Scavenger Model 1925, but you do not document the results. Furthermore, you could not provide the results of your acceptance activities for your receipt of components for your Passive Gas Scavenger Model 14600/14600E.
4. Failure to establish procedures for identifying training needs and for ensuring that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). You could not provide written training procedures during the inspection and a training record for an employee who has been employed for six months.

FDA has reviewed the modifications made to the Active Gas Scavenger Model 1925 cleared for marketing under premarket notification (510[k]) submission number K963601. Since the device was cleared, the Active Gas Scavenger Model 1925's [REDACTED] was [REDACTED]. Test data collected during the inspection do not match the data collected from an unmodified device. This indicates that the new [REDACTED] affects device functionality. This modification represents a significant change that could significantly affect the safety or effectiveness of the device and thus requires submission of a new 510(k) as required by 21 CFR 807.81(a)(3)(i).

You also provided information to FDA during your inspection regarding the preamendment status of the Passive Gas Scavenger Model 39951, currently sold as the Passive Gas Scavenger Model 14600-E. FDA evaluates the preamendment status of a device in accordance with the Preamendment Status policy, as updated on July 14, 2006, found at <http://www.fda.gov/cdrh/comp/preamend.html>. This policy describes the

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documentation that may be submitted to FDA for review of whether a device was commercially distributed prior to May 28, 1976 with specific indications for use. However, FDA does not need to review the sufficiency of the information you provided concerning the preamendment status of the Passive Gas Scavenger Model 39951 because you have substantially changed the Passive Gas Scavenger Model between 1976 and the present when the device transitioned from the original Model 39951 to the Model 5500 to the current Model 14600-E. Specifically, the Passive Gas Scavenger Model 14600-E incorporates the [REDACTED] in place of the [REDACTED] and a change in [REDACTED]. These modifications represent significant changes that could significantly affect the safety or effectiveness of the device and thus require submission of a new 510(k) as required by 21 CFR 807.81(a)(3)(i).

Therefore, the Gas Scavenger (Passive and Active) devices are adulterated under section 501(f)(1)(B) of the Act [21 U.S.C. 351(f)(1)(B)] because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g).

The devices are also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the agency (21 U.S.C. 807.81(b)).

The kind of information you need to submit in order to obtain approval or clearance for your device is described on the internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

You 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 Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all 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 deviations 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 (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations,

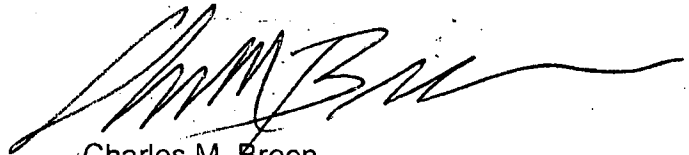
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including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. A follow up inspection will be required to assure that corrections are adequate.

Your response should be sent to: Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have any questions about the content of this letter please contact: Lisa M. Elrand at (425) 483-4913 (tel.) or (425) 483-4760 (fax).

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

Sincerely,

A handwritten signature in black ink, appearing to read 'C. M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen  
District Director