K970035

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EXHIBIT #1
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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

   Graham-Field, Inc.
   400 Rabro Drive East
   Hauppauge, NY 11788

   Date Summary Prepared: December 30, 1996

2. **Name of the Device:**

   John Bunn Neb-U-Lite II™ Medication Compressor with Disposable Nebulizer, Model #JBO-112-009

3. **Predicate Device Information:**

   DeVilbiss Model 4650D Compressor Nebulizer, K#931015

4. **Device Description:**

   This piston-driven nebulizer contains vents in the two sides and bottom of the case providing ventilation for the motor. The compressor has only one control - a double pole toggle switch to turn the compressor on and off. The unit has a two-wire power cord with polarized plug, an internal fuse, and no exposed metal that is likely to become energized (two screws that hold the case together are greatly recessed on the bottom surface and are not likely to become energized). In use, the compressor is placed on a flat surface and the cover is opened to reveal an outlet hose barb to which the oxygen (air) delivery tubing

and nebulizer are connected. Inlet air to the compressor passes through a replaceable filter.

Distributed with the device will be nebulizers purchased from one of the following two (2) companies:

a) Hospitak, Inc.
1144 Route 109
Lindenhurst, NY 11757
K#791536
Product: Power Mist™ Disposable Medication Nebulizer

b) B&F Medical Products
P.O. Box 3656
1421 N. Expressway Drive
Toledo, OH 43608
This nebulizer is pre-amendment for B&F.
Product: Aero/Mist Set

5. Intended Use:

This nebulizer compressor is an AC-powered air compressor intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma, allergies, etc.

6. Comparison to Predicate Devices:

Both devices are AC-powered, contain the same filter material, meet UL1431 and are in the same compressor operating pressure and liter flow ranges. Performance characteristics are basically the same. Both are fairly lightweight, with the John Bunn compressor being lighter and smaller.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The following testing was conducted by CITECH:

a. Electrical Supply

b. Thermal Safety

c. High and Low Temperature Operation

d. High and Low Power Line Voltages

e. Storage at High and Low Temperatures

f. Liquid Spillage

g. Mechanical Vibration and Shock Resistance

h. Mechanical Impact

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was CITECH's conclusion that the John Bunn Neb-U-Lite II™ Medication Compressor with Disposable Nebulizer, Model #JBO-112-009 device sample tested met all relevant requirements of the aforementioned test.

In addition, the following testing was conducted by CITECH:

a. Radiated and Conducted Electromagnetic Energy and Magnetic Field Testing on the John Bunn Neb-U-Lite II™ Medication Compressor with Disposable Nebulizer, Model #JBO-112-009. Testing was conducted per the DCRND Reviewer's Guideline, November 1993.

b. An electrical evaluation performed in accordance with the DCRND Reviewer's Guideline, November 1993 and IEC 801-4 and IEC-801-5 was performed on the John Bunn Neb-U-Lite II™ Medication Compressor with Disposable Nebulizer, Model #JBO-112-009.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

We have demonstrated that the John Bunn Neb-U-Lite II™ Medication Compressor with Disposable Nebulizer is as safe and effective as predicate devices presently on the market, based on electrical, mechanical and environmental results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions". We also adhered to FDA's DCRND "Reviewer Guidance for Home Use Respiratory Devices".