K983736

NOV 10 1998

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: K983736

1. **Submitter's Identification:**

Walter Azevedo Hormann
Brasamerica Medical Equipment, Inc.
3046 Virginia Street
Miami. FL 33133
Tel: (305) 567-0840

Date Summary Prepared: October 20, 1998

2. **Name of the Device:**

ICEL Evolusonic Portable Ultrasonic Nebulizer

3. **Predicate Device Information:**

The ICEL Evolusonic Portable Ultrasonic Nebulizer is substantially equivalent to the ICEL Ultrasonic Nebulizer Model PU 12000 Air and PU 12300 Air previously cleared under K#972371.

4. **Device Description:**

The ICEL Evolusonic Portable Ultrasonic Nebulizer has been developed with the patient's necessities in mind for the delivery of spray liquids in aerosol form into gases directly to the patient for breathing, for use by the adult and pediatric populations.

The device runs on standard AC power and easily upgrades to battery operation (rechargeable battery or sold separately).

It can be plugged into an electrical outlet using the AC/DC converter, and it can also be plugged directly into an automobile cigarette lighter for use when traveling.

5. **Intended Use:**

This ultrasonic nebulizer is intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing for use by both the adult and pediatric populations.

6. **Comparison to Predicate Devices:**

The two (2) devices are identical with regard to theory of operations, indications for use and basic operating procedures. The primary difference (significant) between the two (2) models is the air flow function – The PU 12300 Air contains the air flow function inside the economatic module, whereas the Evolusonic has the air flow function built-in. The intensity controller is indicated by LED (high or low) lighted, whereas the Evolusonic is indicated by LED flashing. Power indication is indicated by LED for the PU 12300 Air, whereas the Evolusonic is indicated by LED flashing in green color, and , the timer for the PU12300 is indicated by LED high/low flashing, whereas the Evolusonic is indicated by LED flashing in an orange color. Software has not been affected. The electrical requirements, power consumption, ultrasonic operating frequency, particle size range and nebulization rate are identical between both devices.

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

(a) Following the methods described in the November, 1993, edition of the FDA's Reviewer Guidance for Premarket Notification Submission, the following electrical and environmental tests were conducted:

- Duration of operation from battery power
  - Electrical power indicators
  - Overcurrent protection
  - Controls protection
  - Connector protective compatibility
  - Mechanical safety
  - Mechanical shock resistance
  - Vibration
  - Fluid spill resistance
  - Extreme operating and storage temperature/humidity

Conclusion: The ICEL ultrasonic nebulizers tested met all relevant requirements of the tests listed in the Reviewer Guidance document, they did not present unsafe conditions.

(b) In addition, in accordance with the Reviewer Guidance document the following EMI testing was also performed:

Reviewer Guidance	Test Description	Test Results
Para. h7ia	Radiated and Conducted Electro-Magnetic Energy	Passed
Para. h7ia	Magnetic Fields	Passed

An electrical evaluation in accordance with the Reviewer Guidance document and IEC 601-1 was performed on the power supply of the ICEL Nebulizer with the following conclusions:

Reviewer Guidance	Test Description	Test Results
Para. (h)(4)	Dielectric Withstand	Passed
Para. (h)(6)	Leakage Current	Passed

(c) In addition a Nebulizer Characterization Study was performed with passing results. The test was conducted in accordance with the Federal Good Laboratory Practices [21 CFR Part 58 (FDA) or 40 CFR Part 160 (EPA)]. All laboratory data which pertains to this study are recorded in Nelson Laboratories Data File Number 57738.

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

No clinical tests were performed and none are submitted with this 510(k) submission.

9. **Conclusions:**

Based upon non-clinical testing performed and the results of such testing, we have demonstrated that the ICEL Evolusonic Portable Ultrasonic Nebulizer is as safe and effective and performs as well as our predicate device cited in this 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1998

Ms. Susan D. Golstein-Falk
Brasamerica Medical Equipment, Inc.
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K983736
ICEL Evolusonic Portable Ultrasonic Nebulizer
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: October 20, 1998
Received: October 22, 1998

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT #B

510(k) NUMBER (IF KNOWN): K983736

DEVICE NAME: ICEL Evolusonic Portable Ultrasonic Nebulizer

INDICATIONS FOR USE:

This ultrasonic nebulizer is intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing for use by both the adult and pediatric populations.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

Linh Modoo 11-9-98

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K983736