K981412

NOV 23 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: K981412

1. **Submitter's Identification:**

Clary Corporation
1960 So. Walker Avenue
Monrovia, CA 91016-4847

Contact Person: Mr. David Fulton, Director, OEM Sales
Date Summary Prepared:

April 16, 1998

2. **Name of the Device:**

M1145 (UPS1-1.25K-1G-MP)UPS

3. **Predicate Device Information:**

Onguard 1000, Catalog No. 04311-000 and 043611-011, Cobe Laboratories, Inc., K#870976

4. **Device Description:**

The M1145 (UPS1-1.25K-1G-MP)Uninterruptible Power Supply (UPS)regenerates new clean, ultra precise AC power to ensure reliable and accurate system operations. It allows for continued operation during generator checks, extended brownouts or complete blackouts.

5. **Intended Use:**

This emergency power source (UPS) is intended for use as a short-term emergency power source for ventilators.

6. **Comparison to Predicate Devices:**

The predicate device's intended use is for emergency power for a cardiopulmonary bypass heart/lung machine system whereas the subject device's intended use is for emergency power for Ventilators.

Most parameters are identical with minor differences in load power factor (.8 lagging vs. .7), and typical back-up time (12 minutes vs. 10 minutes). Output power for the predicate is 1000 VA vs. 1250 VA for the subject device.

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

Testing information demonstrating safety and effectiveness of the Model M1145 (UPS1-1.25K-1G-MP) UPS in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

We conducted UL544 and UL1778 testing on the M1145 (UPS1-1.25K-1G-MP) UPS.

The following testing was conducted by a contract testing laboratory:

a. Vibration, Shock, Fluid Spill Tests
b. Temperature and Humidity Tests

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was the contract testing laboratory's conclusion that the M1145 (UPS1-1.25K-1G-MP) UPS tested met all relevant requirements of the aforementioned test.

In addition, the following testing was conducted by a contract testing laboratory and met all requirements.

a. Radiated and Conducted Electromagnetic Energy and Magnetic Field Testing on the M1145 (UPS1-1.25K-1G-MP) UPS. 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 601-1 was performed on the M1145 (UPS1-1.25K-1G-MP) UPS by a contract testing laboratory.

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

Non-applicable

9. **Conclusions:**

The Clary M1145(UPS1-1.25K-1G-MP)UPS has similar technological characteristics as the predicate device except intended use for the Clary UPS is for emergency power for ventilators vs. emergency power for a cardiopulmonary bypass heart/lung machine for the predicate. All non-clinical testing revealed no new questions of safety or effectiveness. Thus, when compared to the predicate device, the Clary device did not incorporate any significant changes in intended use, method of operations, material or design that could affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1998

Ms. Susan D. Goldstein-Falk
Clary Corporation
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 410
Great Neck, NY 11021

Re: K981412
M1145 (UPS1-1.25K-1G-MP) UPS
Regulatory Class: II (two)
Product Code: CBK
Dated: September 16, 1998
Received: September 18, 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

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

Enclosure

510(k) Number (if known): K981412

Device Name: M1145 (UPS1-1.25K-1G-MP) UPS

Indications For Use:

This emergency power source accessory (UPS) is intended for use as a short-term emergency power source for ventilators, for hospital use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number ____

(Optional Format 1-2-96)