NOV 19 2008

Exihibit #2

510(K)Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of CFR 807.92

The assigned 510(k) number is : K072634

1. Submitter's identifications :

EMG Technology Co. , LTD
4F-2, No.210 , 38RD., Taichung Industrial Park, Shituen Chiu, Taichung, Taiwan , R.O.C.
TEL : 886-4-23596033
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510(k) owner's name :
General Manager/ Mr. Roger Huang

Contact person :
Sally Chuang
Email: Sally@emgtech.com.tw
Date of Summary Preparation: May 08,2007

2. Trade Name, Common Name, Classification of the Device :

Trade Name Including Model Number of Device :
EMG TRITON-COMP., Model NCA01-XXX Series
Common Name or Classification Name : Portable Air Compressor
Classification Code : BTI
Device Class: II

3. Information of the 510(k) Cleared Device(Predicate Device) :

1) Compressors, Air, Mini-Silent (Model BA-400A), 510(k) Number : K#781213
2) Maxi Compressor (Model 501), 510(k) Number : K#900686
3) DeVilbiss Heavy-Duty Compressor (Model 8650D)/
510(k) Number: K#963349

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4. Device description :

The EMG TRITON-COMP. Is a compressor designed for continuous, high pressure performance, easy and practical for home and hospital use. It is capable of servicing nebulizers and humidifiers to produce particle aerosol mist.
The EMG TRITON-COMP. Powered by AC current (115V 60Hz) through the wall electric outlet at home, Maximum constant working pressure at 50psi, delivering up to 22LPM of flow (at pressure 10psi) and does not need software to drive.

The outlet compressed air pressure of EMG TRITON-COMP. is produced through a built-in compressor. The consist parts include motor, cylinder, piston connecting rod, cup seal, eccentric crank, inlet valve, outlet valve ---etc.
When turns on the compressor, motor starts to run and its shaft drives the eccentric crank to actuate the piston connecting rod moving up and down in the cylinder.

When the piston is being in the down strike, a vacuum pressure is produced in the cylinder, then the air will be sucked into the cylinder through an one-way inlet port. When the piston is being in the up strike, it presses out the air through the other outlet port to the atmosphere, these two one-way ports avoid the air being sucked from the atmosphere as well as the air in cylinder being pressed back to the inlet port. When motor keeps running, then the compressed air through outlet port is produced.

One set of iron cover with protective earth encloses the compressor and wire harness to protect user from electrical shock and mechanical hurt hazard.

The operating interface includes: a power switch, a compressed air pressure regulator, pressure gauge and air outlet port. The pressure regulator connected to the air outlet tube of compressor. The pressure gauge and the compressed air outlet port are connected to the pressure regulator through a three way connector and inner tube. Device's compressed air pressure can be adjusted by tuning the knob of pressure regulator, accuracy within +/-5%. The pressure gauge display the pressure data during operation.

The device is designed and manufactured to comply with UL60601-1, CSA C22.2 No.601.1-M90 and EMC (IEC60601-1-2, the requests of the review guidance excerpts related to EMI from November 1993) safety standards and the

performance validation test includes: Pressure Gauge Accuracy Test, Comparative Compressor Flow rate, Air Intake Filter Test, Emitted Particulate, and Air Analysis for the EMG Air-Compressor Model EMG-NCA01, demonstrates EMG Air-Compressor is the same as the predicate device.
The following questions outlined in the Reviewer Guidance For Nebulizers, Metered Dose Inhalers, Spacers and Actuators Guidance are answer as follows:

1) Is the device life-supporting or life-sustaining?
No

2) Is the device an implant?
No

3) Is the device sterile?
No

4) Is the device for single use?
Reusable. EMG TRITON-COMP. dose not contact the body directly, It delivers air indirectly to applied part.

5) Is the device for prescription use?
Yes

6) Is the device for home use or portable?
Portable (operating, storage ambient:: room temperature preferred)

7) Does the device contain a drug or biological product as a component?
No

8) Is this device a kit?
No

9) Is the device software-driven?
No

10) Is the device electrically operated?
Yes, AC 115V 60Hz

11) Are there applicable standards for this device to which conformance has been Demonstrated in addition to those already mentioned(e.g., IEC, ANSF, etc.)?
No

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5. Intended Use :

The device is a portable air compressor intended to provide compressed air for medical purposes.

It is used with a pneumatic nebulizer to administer humidified air or medication to the patient.

The device is intended for use on adult and pediatric patients in a home health care or institutional environment. It's not approved for use with ventilators.

6. The technological characteristics comparison to Predicate Devices :

Attached as exhibit#5 is our technical comparison between EMG TRITON-COMP. and predicate device.

EMG TRITON-COMP. has same intended use, similar performance and comply with same harmonize standard requirements .

7. Discussion of Non-Clinical Tests performed for Determination of Substantial Equivalence are follows :

From the substantial equivalence comparison together with the available harmonize standard test report.

Shows the EMG Triton-Comp. is same as the predicate device .

8. Conclusion :

In terms of EMG TRITON-COMP. have the same construction, function, safety and effectiveness and intended use as the 510(k) predicate device .

The EMG TRITON-COMP. is substantially equivalent to other legally market portable air compressor used for this application .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EMG Technology Company, Limited
C/O Mr. Casey Conry
Responsible Third Party Official
Underwriters Laboratories Incorporated
7 Stuart Road
Chelmsford, Massachusetts 01824

NOV 19 2008

Re: K072634
Trade/Device Name: EMG TRITON-COMP., Model NCA01-XXX Series
Regulation Number: 21 CFR 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI
Dated: October 31, 2008
Received: November 4, 2008

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072634

Device Name: EMG TRITON-COMP. , Model NCA01-XXX Series

Indication For Use:

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Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072634