K113549

510(k) Summary

FEB 2 1 2013

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 01/02/2013

1. Company making the submission

	Submitter
Name	SEOIL PACIFIC CORP.
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2. U.S Agent/Contact Person

Priscilla Chung
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3. Device

Trade Name: Comfort Cough (SICC2001)
Common Name: Secretion Clearance Device
Classification: Class II
Classification regulation: 21 CFR 868.5905
Product Code: NHJ

4. Predicate Device:

Emerson Cough Assist by J.H. Emerson Co. (K002598)
Pegaso Cough by Dima Italia SRL (K072292)

5. Description:

The Comfort Cough is a portable electric device which utilizes a blower and a valve to apply alternately a positive and then a negative pressure to a patient's airway in order to assist the patient in clearing retained bronchopulmonary secretions. It includes a means to adjust the pressure and suction levels applied, a pressure gauge to measure the pressures, and a means to reduce the positive pressure flow. The Comfort Cough system includes accessories such as a breathing hose, a face mask, an adapter and a power cable, but not a bacteria filter. The Comfort Cough can be used with a 510K cleared bacteria filter made by other manufacturers. The compatible size information is specified in the manual.

6. Indication for use:

For use on any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease.

It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube.

- Clinical Settings: For use in a hospital / institutional environment, or in the home, given adequate training and a physician's prescription.

- Patient Population: For use on children and adults. It should not be used on neonates and infants.

- Contraindications: Any patient with a history of bullous emphysema, known susceptibility to pneumothorax or pneumomediastinum or known to have had any recent barotrauma, should be carefully considered before use.

7. Performance Data

- The Comfort Cough has been tested and found to comply with IEC/EN60601-1 and 60601-1-2.
- A side by side testing was performed on the Comfort Cough and the Cough Assist (K002598) to compare pressure and flow rate. The test results show that the two devices have similar performance.
- Several tests have been conducted to check if the device emits a significant amount of volatile organic compounds(VOCs), carbon monoxide(CO), carbon dioxide(CO_2), particulate matters and/or ozone(O^3). The tests were performed in accordance with the following reference methods.
  - US EPA TO-15
  - 21 CFR 801.415

- OSHA(U.S Department of Labor Operation Safety and Health Administration) Method ID-214
- NIOSH (National Institute of Occupational Safety & Health) 0600

The test result has shown that the Comfort Cough does not emit a significant amount of toxic substances which may cause harmful effects on patients.

8. Summary of Technological Characteristics

The Comfort Cough is substantially equivalent to the predicate devices as described below.

Similarities:

1) The devices have the same Indications for Use.
2) With the same fundamental technology, all three devices produce positive and negative pressures to simulate a patient's cough reflex in a controlled manner.
3) The devices comply with IEC 60601 standards for electrical safety.
4) Pressure developed for positive and negative values are comparable.
5) They have electronically powered blowers to generate pressure.
6) They have user interface to adjust to produce positive and negative pressures.
7) The devices simulate a cough using "mechanical insufflation-exsufflation". This is achieved in the devices by applying a positive pressure to the airway initially and rapidly shifting to a negative pressure. The change in pressure effect produces a high expiratory flow from the lungs.
8) The devices can be operated in a manual or in an automatic mode.

Differences:

1) Inhalation, exhalation and pause times differ. The subject device and the Emerson controls these events to 0 to 5 seconds; whereas, the Pegaso Cough controls them from 0.1 to 9.9 seconds.
2) The unit weight of the subject device and the Pegaso is almost half less than the Emerson unit through use of light weight materials.
3) The subject device and the Pegaso Cough is software controlled whereas the Emerson device is controlled by electrical switches.

9. Basis for Substantial Equivalence

Upon reviewing the safety and effectiveness information including testing data provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Comfort Cough is determined to be by SEOIL PACIFIC CORP. to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

Seoil Pacific Corporation
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck Street, Unit J
FULLERTON CA 92833

Re: K113549
Trade/Device Name: Comfort Cough (SICC2001)
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHJ
Dated: February 6, 2013
Received: February 11, 2013

Dear Ms. Chung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, DDS, MA
Mary S. Runner
2013.02.21
13:07:48 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113549

Device Name: Comfort Cough (SICC2001)

Indications For Use:

For use on any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease.

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Prescription Use _√_ **AND/OR** **Over-the Counter Use** ___
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal -S for LS

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

510(k) Number: K113549