K122610

PLAXTRON INDUSTRIAL (M) SDN. BHD.

510 (K) Summary

August 5, 2013

5.1 Device Trade Name:	PLAXTRON CPAP System, Model CH-FFM-87XX, **ERGO EMERGENCY CPAP SYSTEM,** /CH-FFM-88XX, **ERGO II EMERGENCY CPAP SYSTEM,** series
5.2 Named and Address of Manufacturer:	PLAXTRON INDUSTRIAL (M) SDN. BHD. plot 28, kawasan perusahaan, jelapang 2, ftz, ipoh, MALAYSIA 30020
Establishment Registration Number:	8044169
Contact Person:	Doris Yang Engineering / Regulatory Affairs Manager Or Leo Chien General Manager Tel: 886-2-26892001 Fax: 886-2-26892468 E-mail: chtwn@ms21.hinet.net
5.3 Device Classification Names/Code/Regulation Number:	Positive end expiratory pressure breathing attachment /BYE/§868.5965
Device Common Name	CPAP flow generator/PEEP Valve
Regulation Description:	positive end expiratory pressure (PEEP) breathing attachment
Review Panel:	Anesthesiology,
Recognized Performance Standard	ISO 5356-1:2004 (BYE)

AUG 0 5 2013

5.4 Predicate Devices:

(a) Boussignac CPAP Device: 510(k) Number: K013884

(b) Pulmodyne CHF Flow Generator: 510(k) Number: K080256

5.5 Device Description

The PLAXTRON CPAP System is a state of the art non-invasive, disposable ventilator support system. It is a venturi type oxygen / air mixture delivery device which provides CPAP pressure with a 50 PSI compressed gas source at a low input flow to a spontaneously breathing patient. The controlled airway pressure provides rapid relief for maximum patient benefit with minimal oxygen consumption. The device is low cost and completely disposable for single patient use and it is highly efficient to run from a low flow source for longer cylinder life. It equips with filters on inhalation and exhalation to provide maximum protection.

5.6 Intended Use

To provide CPAP to spontaneously breathing adult (>30kg) patients in the hospital and pre-hospital (EMS) environment.

5.7 510(k) Statement

A 510(k) statement for the new device, as required by 21 CFR 93, is replaced with this 510(k) summary.

5.8 Substantial Equivlance

The Plaxtron CPAP System is substantially equivalent in indications for use, environment of use, patient population, and functions (gas flow provided by, Operating Principle, Peak Inspiratory Flow, Display(optional manometer)) to the Boussignac CPAP Device and Pulmodyne CHF Flow Generator identified as the predicate devices. The technologies are similar to the Pulmodyne CHF Flow Generator, by the adjustable valve to generate intended CPAP setting and both with the antisuffocation valves , and are different to Boussignac CPAP Device to generate intended CPAP setting by a venturi virtual valve and without antisuffocation valve. The difference among the predicated devices are the CPAP pressure range: Plaxtron CPAP valve with the range up to 15 cmH_2O, Boussignac CPAP Device with the range up to 10 cmH_2O and Pulmodyne CHF Flow Generator with the three step range in 0-10 cmH_2O or with the variable step range in 0-20 cmH_2O.
In biocompatibility, the Plaxtron CPAP System with the same intended patient face skin contact (by the non-sterilized, CPAP mask) and the same external gas communicate pathway (by the flow generator, the mask frame, the Filter, the corrugate tube and the CPAP Valve with adjustable PEEP) to the Pulmodyne CHF Flow Generator all met corresponding ISO 10993 requirements except that the Pulmodyne CHF Flow Generator CPAP mask can be cleaned and reusable. The cushion mask of the Plaxtron CPAP System is equivalent to the one of the Boussignac CPAP Device to meet corresponding ISO 10993 requirements.

A complete comparative table is as below:

	PLAXTRON CPAP System	Boussignac CPAP Device	Pulmodyne CHF Flow Generator
510(k)	K122610	K013884	K080256
Intended Use	The PLAXTRON CPAP System is intended to provide CPAP to spontaneously breathing adult (>30kg) patients in the hospital and pre-hospital (EMS) environment.	The Boussignac CPAP Device is intended to provide a constant airway positive pressure for spontaneously breathing patients.	The Pulmodyne CHF Flow Generator is intended to provide CPAP to spontaneously breathing adult (>30kg) patients in the hospital and pre-hospital (EMS) environment.
Environments of Use	Hospital, pre-hospital (EMS) environments	Hospital, pre-hospital (EMS) environments	Hospital, pre-hospital (EMS) environments
Patient Populations	spontaneously breathing adult patients (>30kg)	spontaneously breathing adult patients	spontaneously breathing adult patients
Gas flow provided by	Wall gas or cylinder	Wall gas or cylinder	Wall gas or cylinder
Operating Principle	oxygen powered venturi entrains room air to provide inspiratory flow	oxygen powered venturi entrains room air to provide inspiratory flow	oxygen powered venturi entrains room air to provide inspiratory flow
Peak Inspiratory Flow	Unlimited (via anti-suffocation valve)	Unlimited (open system)	Unlimited (via anti-suffocation valve)
Pressure Regulation	(threshold resistor) adjustable valve acts as pressure release valve when expiratory pressure is reached, limiting system pressure to intended setting	(orificial resistor) resulting output flow from venturi creates expiratory resistance and subsequent increased expiratory pressure	(threshold resistor) 3 step adjustable PEEP valve OR single step PEEP valves act as pressure release valve when expiratory pressure is reached, limiting system pressure to intended setting
CPAP pressure range (cmH_2O)	Up to 15 cmH_2O	Up to 10 cmH_2O	0-10 cmH_2O (three step valve, 5.0/7.5/10.0

			cmH_2O) 0-20 cmH2O (variable valve, 2.5/5.0/7.5/10.0/12.5/15.0/20.0 cmH_2O).
Display	Manometer (optional, for CH-FFM-87XX) (Built-in, 0-40 cmH_2O, for CH-FFM-88XX)	Manometer (optional)	Manometer (optional)
Antisuffocation valve	With antisuffocation valve	None, open design allows patient to breath in event of source gas failure	With antisuffocation valve
Excessive pressure relief	for CH-FFM-87XX, Integrated pop-off adjustable up to 15 cm H_2O limits airway pressure to the adjusted pressure in case of un-intentional exhaust port blocked Excessive pressure relief from the PEEP valve	No excessive pressure relief	Excessive pressure relief from the PEEP valve
Patient Interface	Adjustable CPAP Mask with Forehead Pads and Comfort Bonnet, Cushion Mask and Silicone Headstrap	Cushion Mask and Silicone Headstrap	Adjustable Face mask with adjustable headgear
cushion mask	PVC, signal-patient use	PVC, signal-use	None
Accessories	Inspiratory and Expiratory Filters, Mask	Mask, Manometer and Nebulizer	Inspiratory Filter, Mask, Manometer and Nebulizer
Flow generator with filter	Polycarbonate (PC)	Polycarbonate (PC)	Polycarbonate (PC)
CORRUGATE	12" corrugate tube	None,	72" corrugate tube

TUBE	for CH-FFM-87XX		for CH-FFM-87XX
CPAP Valve	PP (CPAP Valve with adjustable PEEP for CH-FFM-87XX)	None,	O2-CPAP Valve
CPAP Masks with head strap	PC mask frame / Silicone mask	None	PC mask frame / Silicone mask
cushion mask	PVC, signal-patient use	PVC, signal-use	None
Requires a flow meter	Yes, with -10 Lpm range	Yes, with -30 Lpm range	Yes, with -50 Lpm range
Input Range	5~10 lpm flow source(for CH-FFM-87XX) 4~8 lpm flow source(for CH-FFM-88XX)	10-25 lpm flow source	15-45 Lpm flow source
Single patient use	All components are single patient use.	Single patient use	The Pulmodyne CHF Flow Generator is multi-patient, reusable and can be cleaned while the other components: circuit, mask, entrainment filter, and PEEP valve are disposable, single patient use.

5.9 Assessment of Non-clinical Performance Data

The PLAXTRON CPAP System has the identical intended use and indication for use as the predicate devices. Substantial equivalence to predicate devices was established by applying the product specification comparison. The requirements and test of the ISO 5356-1:2004. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Considering the risk in re-breathing of CO_2, the CO_2 clearance Testing is performed. The input flow used to drive the ERGO Emergency CPAP generator is small than the predicated device but sufficient to prevent accumulation of exhaled carbon dioxide. The basis of the pressure generator is through the use of a venturi. The Bernoulli principle describes the entrainment of air during a continuous flow of compressed gas. The venturi used in the ERGO Emergency CPAP System entrains significantly more air per liter of oxygen than the predicate device. The venturi used in the ERGO

Emergency CPAP System is considerably strong and the total flow generated at 5 Lpm input flow in the ERGO Emergency CPAP System can provides a combined air/oxygen flow that is sufficient to flush the system of exhaled carbon dioxide. The test result shows that the performance specification of the Plaxtron CPAP system is met the requirements of design specifications for which it is intended in clearing the exhaled CO_2 at input flows of 5 Lpm and the risk of the CO_2 rebreathing is mitigated and acceptable .

Biocompatibility testing is identified by FDA guidance G95-1 that the biocompatibility is the same to the predicated device and US FDA Draft Guidance for Industry and Food and Drug Administration Staff, April 23, 2013, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" The device is identified with the skin surface contact and external communication device (with the gas pathway), and with limited duration that the Cytotoxicity, Sensitization and the Irritation or intracutaneous reactivity are the major biological effect identified and tested. Results from this testing provide assurance that the proposed device is biocompatibile.

5.10 Summary of Conclusion

The PLAXTRON CPAP System is demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device and is substantially equivalent to the predicated devices, in terms of intended use, principle of operation, technological characteristics, and performance characteristics to the listed predicates.

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

August 5, 2013

Plaxtron Industrial (M) SDN. BHD
C/O Ming-Yie Jan, Ph.D.
Sen Mu Technology Company, Limited
No. 15-2, Lane 26, Mincyuan 1st Rd, Lingya District
Kaohsiung City 802, Taiwan R.O.C.

Re: K122610
Trade/Device Name: Plaxtron CPAP System
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive end expiratory pressure breathing attachment
Regulatory Class: Class II
Product Code: BYE
Dated: July 22, 2013
Received: July 30, 2013

Dear Dr. Jan:

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.

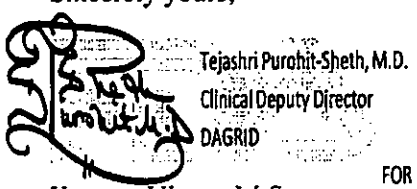
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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,



FOR

Kwame Ulmer, M.S.
Acting Division 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): K122610

Device Name: PLAXTRON CPAP System

Indications for Use:

The PLAXTRON CPAP System is to provide CPAP to spontaneously breathing adult (>30kg) patients in the hospital and pre-hospital (EMS) environment.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neha Gujarati
For Lester Schultheis
2013.08.02 14:51:16 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: K122610