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JAN 28 2011

KOO (Shanghai) Industries Co., Ltd.
100 Zhongde Road, Dakun Industrial Park
Songjiang Shanghai 201614 China

T – 011 86 21 57858410
F – 011 86 21 57858410 x.107

Official Contact: Chris Koo - President

Proprietary or Trade Name: Fisio Chamber Spacer

Common/Usual Name: Spacer / Holding Chamber

Classification Name: Holding Chambers, Direct Patient Interface
NVP - CFR 868.5630

Predicate Devices: K010680 – CT Spacer
K070674 – Trudell AeroChamber Plus

Device Description:
The Fisio Chamber Spacer is intended for use in the inhalation of medications delivered via an MDI and for which the medication is to be delivered to the upper and lower respiratory system. The device consists of a translucent housing and mouth piece or face mask and a one-way valve to prevent exhaling into the chamber.

The Fisio Chamber Spacer is intended to be used to inhale aerosolized drugs of approved MDIs from the following groups of active substances:

- Corticosteroids (anti-inflammatory medications)
- Anti-cholinergics and β2-sympathomimetics (bronchodilater medications)
- Non-steroidal chromones (DNCG)

It is a single patient, multi-use non-sterile device.

Indications for Use:
The Fisio Chamber Spacer is intended to be used by patients who are under the care of treatment of a licensed healthcare professional or physician. The device is intended to be used by these patients to administer aerosolized medication from pressurized Metered-Dose Inhalers, prescribed by a physician or healthcare professional

Patient Population: Any individual

Environment of Use: Home care, nursing homes, sub-acute institutions, and hospitals

Contraindications: None

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Comparison to Predicates

Attribute	510(k) K010680 Clinical Technologies CT Spacer	K070674 Trudell Medical AeroChamber Plus	Proposed Koo Spacer
Intended Use	For use with MDIs	For use with MDIs	For use with MDIs
Indications for Use	The CT Spacer is a spacer used with a MDI or a nebulizer to deliver inhalable drug aerosols to a patient. The spacer is to be used by a single patient, for a maximum of 28 days.	The AeroChamber Plus® a VHC with Flow-Vu® IFI is intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. The intended environments for use include the home, hospitals and clinics.	The Fisio Chamber Spacer is intended to be used by patients who are under the care of treatment of a licensed healthcare professional or physician. The device is intended to be used by these patients to administer aerosolized medication from pressurized Metered-Dose Inhalers, prescribed by a physician or healthcare professional
Environments of use	Not specified	Home, hospitals and clinics.	Home care, nursing homes, sub-acute institutions, and hospitals
Prescriptive	Yes	Yes	Yes
Patient population	Not specified	All	All
Single patient, multi-use	Yes	Yes	Yes
Patient interface	Mouthpiece Face Mask	Mouthpiece Face Mask	Mouthpiece Face Mask
Basic components	Housing One-way valve to prevent exhalation into chamber End caps - removable	Housing One-way valve to prevent exhalation into chamber End caps – removable	Housing One-way valve to prevent exhalation into chamber End caps - removable
Performance testing		Particle characterization Comparison results found to be equivalent	Particle characterization Mechanical Environmental Simulated life cycle (cleaning) ISO 10993 testing

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Substantial Equivalence Discussion

The above table compares the key features of the proposed Fisio Chamber Spacer with the identified predicates and demonstrates that the device can be found to be substantially equivalent.

In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are nearly identical form the proposed device when compared to the predicates - K010680 – CT Spacer and K070674 – Trudell AeroChamber Plus.

Each device is indicated for use with MDIs of the same category of medications.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicate – K010680 – CT Spacer. This design incorporates a housing, end caps, one way valve for inhalation, patient interface of either a mouthpiece or face mask.

Environment of Use –
The environments of use are identical to predicate - K070674 – Trudell AeroChamber Plus.

Patient Population –
The patient population is equivalent to the predicate - K070674 – Trudell AeroChamber Plus.

Comparative Performance –

We performed comparative particle characterization testing via Cascade Impactor and the results demonstrated equivalent performance to the predicate K070674 – Trudell AeroChamber Plus.

In addition, we performed testing related to simulation life / cleaning validation, environmental and mechanical testing. The results demonstrated that the proposed device either passed or met its performance specifications after each test

All testing demonstrated that the proposed device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Koo (Shanghai) Industries Company, Limited
C/O Mr. Paul Dryden
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

JAN 28 2011

Re: K101136
Trade/Device Name: Fisio Chamber Spacer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVP
Dated: January 5, 2011
Received: January 10, 2011

Dear Mr. Dryden:

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,

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

Enclosure

Indications for Use Statement

510(k) Number: **K101136**

Device Name: **Fisio Chamber Spacer**

Indications for Use:

The Fisio Chamber Spacer is intended to be used by patients who are under the care of treatment of a licensed healthcare professional or physician. The device is intended to be used by these patients to administer aerosolized medication from pressurized Metered-Dose Inhalers, prescribed by a physician or healthcare professional.

Environments of use - Home care, nursing homes, sub-acute institutions, and hospitals

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K101136