Re:K122060

MAR 2 1 2013

510(K) SUMMARY

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

The Assigned 510(k) number is: _____

1. Submitter's Identification:

TaiDoc Technology Corporation
3F,5F, No.127, Wugong 2nd Rd., Wugu Dist., New Taipei City, 24888, Taiwan

Correspondence:
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Regulatory Affairs Specialist
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Prepared date: June 30, 2012

2. Device name:

Proprietary name: Clever TD-7001 Nebulizer

Regulatory information:

A. Regulation section: 21 CFR § 868.5630
B. Classification: Class II
C. Product Code: CAF, nebulizer (direct patient interface)
D. Panel: Anesthesiology

3. Indication for Use:

The Clever TD-7001 Nebulizer is an ultrasonic (vibrating mesh) nebulizer system

designed to aerosolize physician-prescribed solution for inhalation by the patient, *except for Pentamidine.*

The Clever TD-7001 Nebulizer is for use with children and adult patients in the homecare environment.

4. Device Description:

Clever TD-7001 Nebulizer is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize physician-prescribed solution for inhalation by the patient. It is for use with children and adult patients in the homecare environment.

Clever TD-7001 Nebulizer consists of a Nebulizer unit, a medication cap and a medication cup. The Nebulizer unit, medication cap and Medication cup are single patient re-usable. The Nebulizer unit contains all control circuitry and is powered by using 2 AA alkaline batteries or an AC adapter which connects to electrical outlets. The patient interface comprises a mouthpiece or mask. The medication cap contains the metal alloy mesh. When the device is turned on, the ultrasonic piezoelectric element vibrate to cause the mesh vibrate. Medication solution in the reservoir of medication cup is aerosolized by the vibrating mesh. The aerosols can be inhaled through the mouthpiece or mask.

5. Substantial Equivalence Information:
   A. Predicate device name: Omron Micro Air Vibrating mesh nebulizer NE-U22
   B. Predicate K number: K062263
   C. Comparison with predicate:

   The proposed Clever TD-7001 Nebulizer has the following similarities to the predicate device which make substantially equivalence:

   - Same intended use
   - Same patient population
   - Same operating principle and working mechanism
   - Same performance efficacy
   - Same fundamental scientific technology

   The differences encompass:

- Physical appearance change
- Mesh cap and medication cup/bottle assemble method
- The connection of electrode from the main unit to the transducer/vibrator
- The material in fluid pathway
- Power requirement and power consumption

6. Performance Characteristics:

1) Aerosol Characterization Testing

The particle size distribution test via Cascade Impactor of Clever TD-7001 Nebulizer was performed in comparison to the predicate device K062263 with three drugs (Ipratropium bromide, Ventolin, and Cromolyn sodium). The test has shown Clever TD-7001 Nebulizer consistent in repeatability tests for each three classes of drug, and demonstrated equivalent performance to the predicate device K062263 that no significant difference ($p \geq 0.05$) in the particle distributions.

Clever TD-7001 Nebulizer has the same performance characteristics as the predicate device and meets its product specification as well.

2) Airpath Testing

Gas sample analysis of Clever TD-7001 Nebulizer has performed and shown the device does not emit potential toxic gases that may cause harmful influences to human, including carbon monoxide, carbon dioxide, ozone, or volatile organic compounds (VOCs). The output of particulate matter conformed to EPA requirements of the PM2.5 standard.

3) Materials

FDA authority considers the gas path contact components the external communicating components with tissue contact. Biocompatibility evaluations of cytotoxicity (ISO 10993-5), irritation (ISO 10993-10), sensitization (ISO 10993-10), implantation (ISO 10993-6) and genotoxicity (ISO 10993-3) tests have been conducted for the gas path contact materials.

4) Safety and EMC

The electromagnetic compatibility and electric safety of the proposed device are tested to meet the following standards:

- EN 60601-1:1988+ A1:1991+ A2:1995
- EN 60601-1-1-2:2001+A1:2006, CISPR 11: 2003

7. Conclusion:

Based on the information provided in this submission, Clever TD-7001 Nebulizer is substantially equivalent to the predicate device in safety and effectiveness.

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

March 21, 2013

Mr. Pinjung Chen
Regulatory Affairs Specialist
TaiDoc Technology Corporation
3F,5F, No.127, Wugong 2nd Road
Wugu District, New Taipei City
Taiwan 24888

Re: K122060
Trade/Device Name: Clever TD-7001 Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: January 31, 2013
Received: February 8, 2013

Dear Mr. Chen:

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,

Kwame O. Ulmer for

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

Re:K122060

Attachment 3. Indications for Use Statement

Indications for Use

510(k) Number: K122060

Device Name: Clever TD-7001 Nebulizer

Indications for Use:

The Clever TD-7001 Nebulizer is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize physician-prescribed solution for inhalation by the patient, *except for Pentamidine.*
The Clever TD-7001 Nebulizer is for use with children and adult patients in the homecare environment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal -S for LS

c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300059331, cn=Albert E. Moyal -S 2013.03.20 12:10:51 -04'00'

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

510(k) Number: K122060