September 13, 2019

Cognita Labs, LLC
Rajoshi Biswas
Architect and Clinical Lead
700 N Main St. Ste C1
Santa Ana, California 92701

Re: K183586
Trade/Device Name: CapMedic
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF, BZG
Dated: August 14, 2019
Received: August 15, 2019

Dear Rajoshi Biswas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James Lee
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183586

Device Name
CapMedic

Indications for Use *(Describe)*
The CapMedic is intended to be used in adults and children 5 years of age and above, who are prescribed CapMedic to be used with their MDIs by their physician.

The CapMedic device is an accessory intended for single-patient use to assist physicians and patients in recording and monitoring the MDI (Metered Dose Inhaler) actuations and conducting PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume for 1 second) spirometry tests. CapMedic measures the parameters of MDI use and records it for review by the physician and/or the patient. Furthermore, CapMedic reminds the patient on important steps of MDI use through audio-visual-haptic cues during their MDI use. With the provided PEF/FEV1 adapter, CapMedic can also perform PEF/FEV1 spirometry test and provides LED feedback based on the measured FEV1. CapMedic can securely transmit MDI usage data and PEF/FEV1 test results to a Bluetooth enabled device running data collection software meeting the CapMedic secure interface protocol over a Bluetooth connection.

CapMedic can be used in the home, work, healthcare, and clinical use environments/settings.

The CapMedic device may also be used in clinical trials where researchers need to know information about the use of MDI medication(s) by a participant.

CapMedic may be used with any of the following MDIs: Ventolin HFA, ProAir HFA, Advair HFA, Flovent HFA, Xopenex HFA, Symbicort HFA, Atrovent HFA, Proventil HFA, Alvesco HFA, Dulera HFA, and Asmanex HFA and is attached with a specific adapter for the MDIs.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K183586 510(k) Summary

September 13th, 2019

Cognita Labs, LLC

700 N Main St. Ste C1

Santa Ana CA 92701

info@cognitalabs.com

This summary of 510(k) information is submitted in accordance with the requirements of 21 CFR 807.92:

(a)(1) Submitter Information

Company	Cognita Labs LLC 700 N Main St Ste C1 Santa Ana California 92701
Contact Person	Rajoshi Biswas, Architect and Clinical Lead
Telephone #	+1-832-538-3042
Date of preparation	September 13, 2019

(a)(2) Name of the Device

Device Name	CapMedic
Common Name	Inhaler Guidance Tool and Home Spirometer (PEF/FEV1)
Product Code and Classification Name	Primary product code: CAF, 21 CFR 868.5630, Class II, Nebulizer Secondary product code: BZG, 21 CFR 868.1840, Class II, Diagnostic spirometer

(a)(3) An identification of the legally marketed devices

The predicate devices to which substantial equivalence is claimed are: K990185, MDILog System MDC-512 marketed by Medtrac Technologies, Inc., K140638, Propeller Model 2 Sensor marketed by Reciprocal Labs Corporation, and K133722 Asthma Monitor AM3 GSM (PEF and FEV1 meter) marketed by eResearchTechnology.

(a)(4) A description of the device

The CapMedic device includes a reusable sensing module that attaches to the Metered Dose Inhaler (MDI) to measure when and how patients use their inhalers. CapMedic has on-board visual, audio and haptic user interfaces (UIs) to remind patients to use their inhaler correctly through UI prompts. The recorded parameters of MDI use are MDI shaking, orientation, coordination between MDI actuation and the start of inspiration, and inhalation duration. During MDI use, CapMedic can provide just-in-time reminders, in the form of UI prompts, for various steps of MDI use, namely, MDI shaking, MDI upright orientation, correct coordination, breathe long and hold breath at the end. CapMedic also optionally provides dosing reminders through UI prompts at times preset by the user.

Further, CapMedic has a built-in peak-flow meter functionality with a separate mouthpiece attachment to the bottom of the sensing module to measure peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV1). CapMedic can securely transmit MDI usage data and PEF/FEV1 test results to a Bluetooth enabled device running data collection software meeting the CapMedic secure interface protocol over a Bluetooth connection. The CapMedic is powered by a rechargeable Lithium Polymer battery and can be charged via a micro-USB cable.

(a)(5) Intended use of the device

The CapMedic is intended to be used in adults and children 5 years of age and above, who are prescribed CapMedic to be used with their MDIs by their physician.

The CapMedic device is an accessory intended for single-patient use to assist physicians and patients in recording and monitoring the MDI (Metered Dose Inhaler) actuations and conducting PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume for 1 second) spirometry tests. CapMedic measures the parameters of MDI use and records it for review by the physician and/or the patient. Furthermore, CapMedic reminds the patient on important steps of MDI use through audio-visual-haptic cues during their MDI use. With the provided PEF/FEV1 adapter, CapMedic can also perform PEF/FEV1 spirometry test and provides LED feedback based on the measured FEV1. CapMedic can securely transmit MDI usage data and PEF/FEV1 test results to a Bluetooth enabled device running data collection software meeting the CapMedic secure interface protocol over a Bluetooth connection.

CapMedic can be used in the home, work, healthcare, and clinical use environments/settings.

The CapMedic device may also be used in clinical trials where researchers need to know information about the use of MDI medication(s) by a participant.

CapMedic may be used with any of the following MDIs: Ventolin HFA, ProAir HFA, Advair HFA, Flovent HFA, Xopenex HFA, Symbicort HFA, Atrovent HFA, Proventil HFA, Alvesco HFA, Dulera HFA, and Asmanex HFA and is attached with a specific adapter for the MDIs.

(a)(6) Technological Characteristics

The CapMedic device is technologically equivalent to the three predicates identified above for the three main functions, MDI use measurement, lung function measurement, and data transfer. For the MDI use measurement functions, the CapMedic is similar to both MDILog system and Propeller sensors for monitoring MDI medication use. Both predicates and CapMedic measure the timestamp of MDI use. MDILog also measures MDI use parameters such as MDI shaking, canister actuation and inhalation, all of which are also measured by CapMedic. All devices are battery-powered. Further, both the Propeller device and CapMedic transfer data using Bluetooth Low Energy. The Asthma Monitor measures spirometry parameters of PEF and FEV1, is battery powered and transfers data through Bluetooth Low Energy, same as CapMedic.

The CapMedic device measures the MDI orientation as an additional parameter of MDI use as compared with MDILog. Further, CapMedic also provides UI prompts to remind the user of the correct steps for MDI use and contains a rechargeable battery. All of these parameters were extensively tested, the performance bench-marked and thorough risk analysis conducted to demonstrate that the difference does not affect the substantial equivalence.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted:

- The MDI use measurement parameters and UI are tested extensively to demonstrate the performance and substantial equivalence.
- The lung function parameters measured by CapMedic have been tested according to the ATS guidance on standardization of spirometry, published in 2005.
- The Aerosol Particle Size Distribution (APSD) and Delivered Drug Uniformity (DDU) tests have been conducted to demonstrate the compatibility of CapMedic's use with the supported MDIs.
- Biocompatibility tests have been conducted and passed according to ISO 10993-1.

- CapMedic has been tested for the electrical requirements: IEC 60601-1:2005 + A1:2012, IEC 60601-1-2:2014, IEC 60601-1-11:2015, IEC 60601-1-8:2006+AMD1:2012, and IEC 60601-1-6:2010+AMD1:2013.
- Bluetooth data transfer and interfaces are tested to comply with "Radio Frequency Wireless Technology in Medical Devices guidance for industry and FDA, 2013" and FDA's guidance on "Management of Cybersecurity in Medical Devices, 2014".
- Additionally, usability testing, software, and system verification activities have been conducted.

  The tests demonstrate the performance and compatibility of CapMedic with the MDIs Ventolin HFA, ProAir HFA, Advair HFA, Flovent HFA, Xopenex HFA, Symbicort HFA, Atrovent HFA, Proventil HFA, Alvesco HFA, Dulera HFA and Asmanex HFA.

(2) A brief discussion of the clinical tests submitted

Clinical testing was not required to determine substantial equivalence of CapMedic.

(3) The conclusions drawn from the nonclinical and clinical tests

Based upon the foregoing performance testing and comparison to the legally marketed predicate devices for indications for use, technology, and performance it is demonstrated that the CapMedic is substantially equivalent to the predicates.