August 30, 2023`

Ochsner Clinic Foundation
Hakm Murad
Bioengineer
1514 Jefferson Hwy
New Orleans, Louisiana 70121

Re: K223367
Trade/Device Name: Ochsner Connected Inhaler Sensor
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: July 10, 2023
Received: July 25, 2023

Dear Hakm Murad:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223367

Device Name
Ochsner Connected Inhaler Sensor

Indications for Use *(Describe)*
The Ochsner Connected Inhaler Sensor System includes the Ochsner Connected Inhaler Sensor. The Sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring actuations of prescribed MDI usage.

The Ochsner Connected Inhaler Sensor Mobile Application records, stores, and transmits usage events from the Sensors to a remote storage system. With the Mobile Application, the user can review information collected from the Sensors and report and review symptoms and other information about their disease management and its impact. The user may also share their information with their caregivers, physicians, and health care providers.

When used with a prescribed MDI, the System can report on information captured during the normal course of use, such as the time between actuations, that can be helpful in assessing MDI technique.

When used under the care of a physician with a prescribed MDI, the System can assist in the management of respiratory health symptoms and exacerbations by providing feedback through reminders, notifications, and self-management education.

The System is intended to be used in populations from Child (>2 years) to adult.

The System can be used both indoors and outdoors; home, work, and clinical settings, as well as on aircraft.

The System may also be used in clinical trials where researchers need to know information about the use of MDI medications by a participant.

The output of the System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The System is not intended for use as an MDI or inhaled medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI or inhaled medication.

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.

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510(k) Summary

Prepared Date:	8/28/23
Submitter:	Ochsner Clinic Foundation 1514 Jefferson Highway New Orleans, LA 70121
Official Contact:	Hakm Murad, Ph.D. Biomedical Engineering Mgr. Ochsner Clinic Foundation 1514 Jefferson Highway New Orleans, LA 70121 5048427785 Hakm.murad@ochsner.org
Trade Name:	Ochsner Connected Inhaler Sensor
Common Name:	Nebulizer Accessory
Classification Name:	Nebulizer
Classification Regulation:	21 CFR §868.5630
Product Code:	CAF
Device Description:	Electronic MDI Accessory
Predicate Device:	Propeller System Model 2 OTC K142516
Intended Use:	The Ochsner Connected Inhaler Sensor System includes the Ochsner Connected Inhaler Sensor. The Sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring actuations of prescribed MDI usage. The Ochsner Connected Inhaler Sensor Mobile Application records, stores, and transmits usage events from the Sensors to a remote storage system. With the Mobile Application, the user can review information collected from the Sensors and report and review symptoms and other information about their disease management and its impact. The user may also share their information with their caregivers, physicians, and health care providers. When used with a prescribed MDI, the System can report on information captured during the normal course of use, such as the time between actuations, that can be helpful in assessing MDI technique. When used under the care of a physician with a prescribed MDI, the System can assist in the management of respiratory health symptoms and exacerbations by providing feedback through reminders, notifications, and self-management education. The System is intended to be used in populations from Child (>2 years) to adult.

The System can be used both indoors and outdoors; home, work, and clinical settings, as well as on aircraft.

The System may also be used in clinical trials where researchers need to know information about the use of MDI medications by a participant.

The output of the System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The System is not intended for use as an MDI or inhaled medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI or inhaled medication.

Technology Comparison and Device Description: The subject device uses technology similar to the predicate device, Propeller System Model 2 OTC, including Bluetooth wireless connectivity which connects to a similar mobile application. Like the predicate device, the Ochsner Connected Inhaler Sensor has an enclosure to fit to inhalers and a button for detecting use.

Technological characteristics of the Ochsner System and the Comparison: Propeller System are largely equivalent. Similarities include the indications for use, basic principle of operation, data collection information, time of data recording via internal clock, utilization of software for varying types of data review and modification, nonrechargable batteries, and the use of Bluetooth, low energy. The Ochsner System employs these technological characteristics in a similar way to the predicate device.

By reviewing the recorded data displayed by the Ochsner System, the physician or care provider can identify that a patient's state is worsening, and as a result, may choose to take action, such as contacting their patient. These aspects of the device have been verified and validated in order to establish equivalent performance to the equivalent device. This information indicates that the Ochsner System is equivalent to the predicate device in terms of device safety and effectiveness.

Comparison Table

Technology Characteristics	**Predicate Device:** Propeller System, Propeller Sensor Model 2 OTC 510(k) Number: K142516	**Candidate Device:** Ochsner Connected Inhaler Sensor 510(k) Number: K223367	**Comparison** N/A
Prescription/OTC	OTC	OTC	Equivalent
Indications for Use	The Propeller System includes the	The Ochsner Connected Inhaler	Similar: The Ochsner

	Propeller MDI Model 2 Sensor. The sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed MDI usage. The Propeller Mobile Application records, stores, and transmits usage events from Propeller Sensors, or via manual user entry, to a remote storage system. With the Propeller Mobile Application the user can review information collected from the MDI sensor, and report and review symptoms and other information about their disease management and its impact. The user may also share their information with their caregivers, physician, and healthcare providers. The Propeller Web Application is software that, like	Sensor System includes the Ochsner Connected Inhaler Sensor. The Sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring actuations of prescribed MDI usage. The Ochsner Connected Inhaler Sensor Mobile Application records, stores, and transmits usage events from the Sensors to a remote storage system. With the Mobile Application, the user can review information collected from the Sensors and report and review symptoms and other information about their disease management and its impact. The user may also share their information with their caregivers, physicians, and health care providers. When used with a prescribed MDI, the System can report on information captured during the normal	Connected Inhaler System does not include a Web Application. The functionalities of the web application are contained entirely within the Ochsner Connected Inhaler Mobile Application since mobile application is necessary for device use. It was determined that there would be no increase in risk for users from this change. Otherwise the IFUs for both products contain the same purpose for the devices, patient populations, and use environments.

	the Propeller Mobile Application, is intended to allow users to review the collected information and characteristics of their MDI and its use, to capture other patient-reported information and outcomes, and to allow that information to be shared with their caregivers, physicians, and health care providers. When together with a prescribed MDI, the system can report on information captured during the normal course of use, such as the time between actuations that can be helpful in assessing MDI technique. When together with a prescribed MDI, the system can be used to reduce the frequency of respiratory health symptoms and exacerbations by increasing adherence to MDI	course of use, such as the time between actuations, that can be helpful in assessing MDI technique. When used under the care of a physician with a prescribed MDI, the System can assist in the management of respiratory health symptoms and exacerbations by providing feedback through reminders, notifications, and self-management education. The System is intended to be used in populations from Child (>2 years) to adult. The System can be used both indoors and outdoors; home, work, and clinical settings, as well as on aircraft. The System may also be used in clinical trials where researchers need to know information about the use of MDI medications by a participant. The output of the System is not	

	medications through the use of feedback such as reminders and notifications, and self-management education. The Propeller System is intended to be used in populations from Child (>2 years) to Adult. The Propeller System can be used both indoors and outdoors; home, work, and clinical settings, as well as on aircraft. The Propeller System may also be used in clinical trials where researchers need to know information about the use of MDI medication(s) by a participant. The output of the Propeller System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The Propeller System is not intended for use as an MDI dose counter, nor is it intended to indicate	intended to diagnose or replace a diagnosis provided by a licensed physician. The System is not intended for use as an MDI or inhaled medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI or inhaled medication.	

	the quantity of medication remaining in an MDI or inhaled medication.		
Design – Attachment to Medication Dispenser	Physically attached to dispenser without inhibiting patient use	Physically attached to dispenser without inhibiting patient use	Equivalent
Principle of Operation	Attaches to the top of the medication canister and performs wireless uploading of usage history of the inhaler	Attaches to the top of the medication canister and performs wireless uploading of usage history of the inhaler	Equivalent
Output Port and Computer Interface	Wireless uploading to database; viewed by PC or other internet-capable devices	N/A	Different: The candidate device is not web-based
Data Collection Technology	Records date and time of MDI usage with button press switch	Records date and time of MDI usage with button press switch	Equivalent
Mobile Platforms	iOS version 7 or higher Android operating system version 4.3 or higher	iOS version 14 or higher Android operating system version 11 or higher	Different: The candidate device supports more recent versions of mobile platforms
Required Off-the-Shelf Hardware	Apple smartphones or devices with Bluetooth, iOS 7 or higher Android smartphones or devices with Bluetooth Internet capable device; no processor or memory	Apple smartphones or devices with Bluetooth, iOS 14 or higher Android smartphones or devices with Bluetooth, version 11 or higher	Similar: The candidate device only works on mobile and thus only requires apple and android hardware.

	requirements (see Required Browser)		
Required Browser	Firefox, Chrome, Safari, Internet Explorer	N/A	Different: The candidate device is not web-based
Mobile Application	Propeller Health Mobile Application records, stores, and transmits usage events from the Propeller Health Sensor via a feature or smartphone and can be used to review the information captured when using a smartphone	Ochsner Connected Inhaler Sensor Mobile Application records, stores, and transmits usage events from the Ochsner Connected Inhaler Sensor via a feature or smartphone and can be used to review the information captured when using a smartphone	Equivalent
Software	The Propeller Health Web Application is software intended to allow users to review the collected information and characteristics of MDI use, to add detail associated with a recorded usage event, and to share that information with their physician in order to provide additional information associated with the condition for which their MDI medication(s) are prescribed.	N/A, not web based. But the mobile application allows the user to share information with their provider and add other details related to their condition for which their MDI medication(s) are prescribed.	Different: The candidate device is not web based. But its mobile application allows the user to share information with their provider and add other details related to their condition for which their MDI medication(s) are prescribed.
Dose Counter	No	No	Equivalent
Records Usage	Yes	Yes	Equivalent
Records Location of Usage (GPS Coordinates)	Geographic coordinates can be captured by the	Geographic coordinates can be captured by the	Equivalent

	wireless device if paired with a Sensor	wireless device if paired with a Sensor	
Keyboard/Input Interface	Dual button interface: primary button and secondary button	Single button interface	Similar: The candidate device also uses buttons as input, but only 1.
Digital Display	No	No	Equivalent
Power Source	Single 3V DC Li-ion battery	Single 3V DC Li-ion battery	Equivalent
Battery Life	1.5 years	1 year	Similar
Low Battery Indicator	Yes, light combination; software display of battery life	Software displays battery life, no on device indicator	Similar: Candidate device only uses software to display battery, while the predicate also has a light-based indicator
Patient Reminder	Yes	Yes	Equivalent
Support	Yes	Yes	Equivalent
Patient Data Storage with Software	Yes	Yes	Equivalent
Patient Data Report Generation with Software	Yes	Yes	Equivalent
Patient Data Graphs Generation	Yes	Yes	Equivalent
Data Retrieval from Device with Software	Yes	Yes	Equivalent
Case Material – Patient Contact by Intact Skin (Hands)	Lexan polycarbonate	Silicon Rubber	Different: The candidate device uses a different but also biocompatible case material
Electrical Safety	IEC 60601	IEC 60601	Equivalent
Biocompatibility	ISO 10993	ISO 10993	Equivalent
Sterility	Non-sterile	Non-sterile	Equivalent

Test Summary:	Test results indicate that the Ochsner Sensor and its predicate Propeller Sensor Model comply with predetermined specifications. Software verification and validation testing confirms this result. Non-clinical testing has been carried out to cover functional verification and device performance. This included completion of software verification and validation procedures, with performance testing of the MDI actuation sensor system to ensure data is logged accurately for MDI usage. This established correct functionality of the Ochsner System according to the requirements. Third party testing of the Ochsner System for compliance to lEC 60601 series standards for general safety and electromagnetic compatibility and ISO 10993 series standards for biocompatibility was completed by accredited laboratories prior to this submission. Complete, detailed reports are included in the application for clearance; summary information is included below. The above testing confirms that the device is substantially equivalent to the predicate device.
Software Testing:	Software and Firmware for the Ochsner System was designed and developed according to a robust software development process aligned with "Design Control Guidance for Medical Device Manufacturers" "The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", "Guidance for Off the Shelf Software Use in Medical Devices", and verified and validated using guidance from the "General Principles of Software Validation" as recommended by FDA. Test results indicate that the Ochsner System complies with its predetermined specifications.
Electrical Safety Testing:	The Ochsner Sensor has successfully completed patient safety testing according to IEC 60601-1.
Electrical Compatibility Testing:	The Ochsner Sensor has successfully completed EMC testing Compatibility according to lEC 60601-1-2.
Performance Testing – Bench:	The Ochsner System has successfully completed performance testing according to applicable standards and internal testing. Important to highlight in this summary, is the successful performance testing that was completed for wireless/Bluetooth technology in accordance with specifications and also with, "FDA's Guidance on Radio-Frequency Wireless Technology in Medical Devices". In addition, tests required for FCC licensing were successful.
Clinical Testing:	No clinical testing was required.
Hazard Analysis for OTC:	Hazard Analysis for OTC included a review of existing hazards as well as how the patient obtains and learns about the system, registers for the system, installs the sensor, uses the Ochsner System to track MDI medication use, shares data with their physician/care team and obtains help & support with OTC labeling. No concerns of safety with the proposed OTC indication were found.

Conclusion: Hardware testing carried out for the Ochsner System indicates it meets design and performance functional requirements. Software verification demonstrates that device features are effective, and that the system configuration functions equivalently to the predicate device. The Ochsner System also meets standard requirements for electrical safety, electromagnetic compatibility, biocompatibility, and wireless technology in medical devices.

Based upon this comparison of the predicate, and the accompanying testing results for the Ochsner Connected Inhaler Sensor, the Ochsner System is substantially equivalent to the predicate device.