July 31, 2020

Safey Medical Devices Pvt Ltd
Taher Moiyed
CEO and Founder
PAP-S-47&48, Chakan MIDC – II,
Pune 410501, Maharashtra India

Re: K201002
Trade/Device Name: Safey Pocket Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG

Dear Taher Moiyed:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 30, 2020. Specifically, FDA is updating this SE Letter as an administrative correction (incorrect contact information).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Rachana Visaria, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, (240) 402-5628 , Rachana.Visaria@fda.hhs.gov.

Sincerely,

Rachana Visaria -S

for Michael Ryan
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

July 30, 2020

Safey Medical Devices Pvt Ltd
Taher Moiyed
CEO and Founder
3rd Floor, Office 303, Nyati Emporius, S no 105 H no 4A,
Baner, Pune, Maharashtra 411045
India

Re: K201002
Trade/Device Name: Safey Pocket Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: June 30, 2020
Received: June 30, 2020

Dear Taher Moiyed:

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,

Rachana Visaria -S

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
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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)*
K201002

Device Name
Safey Pocket Spirometer

Indications for Use *(Describe)*
Safey Pocket Spirometer is a spirometer intended to be used by a patient under the instruction of a physician to perform basic lung function and spirometry testing for users above 5 years of age in home healthcare environment.

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

1) Applicant Information

Manufacturer	Safey Medical Devices Pvt Ltd PAP-S-47&48, Chakan MIDC – II, Pune 410501, Maharashtra India
Contact Information	Taher Ali Moiyed, CEO and Founder taher@safeymedicaldevices.com +44 7855 535353
Date of preparation	07/29/2020

2) Device Information

	Subject Device
Proprietary name	Safey Pocket Spirometer
Common Name	Spirometer
Classification	Diagnostic Spirometer Regulatory Class II; per 21 CFR 868.1840 Product Code: BZG
Predicate Device	Spirobank G (K072979)

3) Device Description

Safey Pocket Spirometer is a prescription use medical device to help respiratory patients keep track of their lung health. This device is a portable spirometer intended for above 5 years of age. Safey Pocket Spirometer is a pocket device intended for home use and operates on two AAA type standard alkaline batteries.

Safey Pocket Spirometer works on infrared interrupt concept. The turbine consists of a vane which rotates clockwise or anti-clockwise depending on the direction of flow into the turbine. The device consists of Infrared pairs which detects the direction and speed of rotation of the vane, which is further calculated to interpretable spirometry values. The device connects with a Medical Mobile Application (Safey App) using BLE (Bluetooth Low Energy) to display the test results to the User.

Mobile Medical Device (Safey App)

Safey Pocket Spirometer connects to the smartphone with Safey App installed using Bluetooth (Low Energy). Upon conducting the tests as per instruction, the test result information is synched to the Safey App in real time. The App displays and stores this information for future use.

The Safey App is also a medication reminder tool. It helps users by reminding to take their medications on time. The Safey App also has the functionality which helps users to connect with friends and family members to share medication reminder related information.

4) Indications for Use

Safey Pocket Spirometer is a spirometer intended to be used by a patient under the instruction of a physician to perform basic lung function and spirometry testing for users above 5 years of age in home healthcare environment.

5) Comparison of Technological Characteristics

The following is a comparison between the predicate and the subject device.

	Spirobank G	**Safey Pocket Spirometer**	**Comparison**
510(k) number	K072979 (Predicate)	K201002	
Intended Use	The Spirobank G spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infants and neonates.	Safey Pocket Spirometer is a spirometer intended to be used by a patient under the instruction of a physician to perform basic lung function and spirometry testing for users above 5 years of age in home healthcare environment.	Substantially Equivalent
Type of Use	Rx	Rx	Same
Classification	BZG	BZG	Same
Use environment	All settings	Home use	Different use environments
Size	109x49x21 mm	95x58x18.12 mm	Different dimensions
Operating Principal	Infrared Interrupts	Infrared Interrupts	Same
Method of communication	Bluetooth Low Energy	Bluetooth Low Energy	Same
Mouthpiece type	Reusable	Reusable	Same
Volume Accuracy	3% or 0.1 L whichever is greater	3% or 0.1 L whichever is greater	Same
Peak Flow Accuracy	10% or 24 L/m (0.40 L/s) whichever is greater	10% or 24 L/m (0.40 L/s) whichever is greater	Same
Power source	2x Alkaline AAA Batteries	2x Alkaline AAA Batteries	Same
Flow and Volume Accuracy Standards	As per ATS/ERS Standards	As per ATS/ERS Standards	Same
IP Rating	IP22	IP22	Same
Maximum peak flow	16 L/s	16 L/s	Same
Test Feedback	Real time feedback and graphical representation of flow	Real time feedback and graphical representation of flow	Same
Display screen	Mobile App	Mobile App	Same

Applicable standards	Electrical Safety IEC 60601–1 Electromagnetic Compatibility IEC 60601–1–2 ATS Standardization of spirometry 1994 Update	Electrical Safety IEC 60601–1 Electromagnetic Compatibility IEC 60601–1–2 IEC 60601-1-6 IEC 60601-1-11 ATS Standardization of spirometry 2005	Same
Measured Values			
Forced vital capacity	FVC	FVC	Same
Volume expired in the first	FEV0.75, FEV1, FEV3, FEV6	FEV0.75, FEV1, FEV3, FEV6	Same
Ratio between volume expired in a certain time period and FVC	FEV/FVC (FER) for 0.75/1/3/6	FEV/FVC (FER) for 0.75/1/3/6	Same
Peak expiratory flow	PEF	PEF	Same
Forced expiratory flow between the first 25% and 75% of the FVC	FEF25-75 (MEF)	FEF25-75 (MEF)	Same
Volume inspired in the first second of the test	FIV1	FIV1	Same
Forced inspiratory volume	FIVC	FIVC	Same
Peak inspiratory flow	PIF	PIF	Same
Forced inspiratory flow in the first 25% and 75% of the FIV	FIF25-75 (MIF25-75)	FIF25-75 (MIF25-75)	Same
Ratio between FEV1 and FEV6	FEV1/FEV6	FEV1/FEV6	Same
Forced expiratory flow at 50% of FVC divided by FVC	FEF50/FVC	FEF50/FVC	Same
Forced inspiratory flow in the first 25% and 75% of the FIV	FIF25-75 (MIF25-75)	FIF25-75 (MIF25-75)	Same
Ratio between FEV1 and FEV6	FEV1/FEV6	FEV1/FEV6	Same
Forced expiratory flow at 50% of FVC divided by FVC	FEF50/FVC	FEF50/FVC	Same
Force inspiratory flow at first	FIV1/FIVC (FIR)	FIV1/FIVC (FIR)	Same

second device forced inspiratory volume			
Forced expiratory time	FET	FET	Same
Maximum voluntary ventilation	MVV	-	Different

Apart from structural differences which do not affect the substantial equivalence of the product, the following are the differences between the subject and predicate device: -

Use Environment

The predicate device is rated for all settings whereas the subject device is rated for home use only. Since the subject device is rated for a more restricted environment compared to the predicate device, it is deemed to be at least as safe and as effective as the predicate device.

6) Performance Data

A series of non-clinical tests are conducted on Safey Pocket Spirometer. They include: -

Standard	Description
IEC 60601-1:2005+AMD1:2012	General requirements for basic safety and essential performance
IEC 60601-1-2:2014(4th Edition)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010, AMD1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-11:2015	General requirements for basic safety and essential performance -Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ATS Standardization of Spirometry	The Safey Pocket Spirometer device was tested on a Flow/Volume Simulator according to American Thoracic Society (ATS) Document “Standardization of Spirometry - 2005”. The results obtained show that Safey Pocket Spirometer display results within ATS limits.
ISO 10993-1	Biocompatibility of the materials has been tested for cytotoxicity, irritation, and sensitization according to ISO 10993-1: 2009, following FDA’s guidance document “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.
IEC 62304	The evaluation of Software Development Life Cycle of the Software programmed into Safey Pocket Spirometer and the Safey App was conducted as per IEC 62304. The software verification and validation was conducted and documented as

	per “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”
FCC Part 15 Subpart B and C	The device was tested as per 47 CFR Part 15 for intentional and unintentional radiators.

All performance tests conducted on Safey Pocket Spirometer were passed.

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA’s Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, and the software for this device was considered as a “moderate” level of concern.

In addition, the following FDA guidance documents were also followed in this submission:

• Radio Frequency Wireless Technology in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, August 4, 2013
• Design Considerations for Devices intended for home Use, Nov 24, 2014
• Postmarket management of Cybersecurity in Medical Devices, Dec 28, 2016

7) Conclusion

Based on these results, it is our determination that the device is substantially equivalent to its predicate device.