November 22, 2022

NDD Medizintechnik AG
Andreas Senn
Director Quality, RA & QA
Technoparkstrasse 1
Zurich, 8005
Switzerland

Re: K221250
Trade/Device Name: EasyOne Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: October 17, 2022
Received: October 21, 2022

Dear Andreas Senn:

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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K221250

Device Name
EasyOne Filter

Indications for Use *(Describe)*
The EasyOne Filter is intended to be used in combination with NDD breathing mouthpieces to reduce bacteria, viruses and other particulates from the patient's exhaled air while performing flow measurements, such as spirometry tests. The EasyOne Filter is a single-use device and intended for single-patient use only.

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

In accordance with 21 CFR 807.92 the following information is provided for the EasyOne Filter.

ADMINISTRATIVE INFORMATION

Date prepared	November 21, 2022
Submission type:	Traditional 510(k)
Purpose of 510(k):	Introduction of a new device. The new EasyOne Filter is a viral, bacterial filter designed to be used with NDD breathing mouthpieces.
Submitter	NDD Medizintechnik AG Technoparkstrasse 1 CH-8005 Zürich Note: NDD stands for New Diagnostic Design
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DEVICE NAME AND CLASSIFICATION

Trade name:	EasyOne Filter
Variants, types:	EasyOne Filter SP EasyOne Filter FT
Common name:	Breathing circuit bacterial filter

Regulation number:	21 CFR 868.5260
Classification name:	Breathing circuit bacterial filter
Regulatory class:	Class II
Product Code:	CAH

PREDICATE DEVICE

Subject Device:	EasyOne Filter
Primary Predicate Device:	VBmax Viral and Bacterial Filter, K000654
Reference Devices:	Air Safety Model 2800 PFT Filter, K051712
	Easy-On PC Spirometer, K090034
	EasyOne Air Spirometer, K161536

INDICATIONS FOR USE

The EasyOne Filter is intended to be used in combination with NDD breathing mouthpieces to reduce bacteria, viruses and other particulates from the patient's exhaled air while performing flow measurements, such as spirometry tests.
The EasyOne Filter is a single-use device and intended for single-patient use only.

DEVICE DESCRITION

The EasyOne Filter is a viral, bacterial filter designed to be used with NDD breathing mouthpieces during flow measurements, e.g. for spirometry testing with NDD spirometers. The EasyOne Filter exists in two variants which differ in the connection interface to enable mounting on the Spirette and on the EasyOne FlowTube. The EasyOne Filter is composed of two injection molded polymeric parts which enclose a filter medium.
The EasyOne Filter is an optional accessory and reduces viruses, bacteria, and other particles that may be released by the patient and thus contaminate the test environment. The EasyOne Filter is non-sterile and for single use.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

Predicate device comparison table				
Criteria	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Predicate comparison results**
510(k) number	K221250	K000654	K051712	Different

Predicate device comparison table				
Criteria	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Predicate comparison results**
Device	EasyOne Filter	VBMax PFT Filter	Air Safety Model 2800	Different
Manufacturer	ndd Medizintechnik AG	A-M Systems	GVS Filter Technology	Different
Regulation number	868.5260	868.5260	868.1840	Same as predicate, different to reference device
Regulation name	Filter, Bacterial, Breathing-Circuit	Filter, Bacterial, Breathing-Circuit	Spirometer, Diagnostic	Same as predicate, different to reference device
Product Code(s)	CAH	CAH	BZG	Same as predicate, different to reference device
Regulatory Class	II	II	II	Same
Intended use	The EasyOne Filter is intended to be used in combination with NDD breathing mouthpieces to reduce bacteria, viruses and other particulates from the patient's exhaled air while performing flow measurements, such as spirometry tests.	The VBMax filter is a disposable, single-patient session filter for spirometric and pulmonary function testing. The VBMax filter is designed to prevent bacterial/viral contamination from entering the pulmonary function equipment. The filter is to be used with children and adults subjects, but it is not indicated for use with neonatal subjects. It is to be	For use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment.	Same

Predicate device comparison table				
Criteria	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Predicate comparison results**
		used under the direction of a physician.		
Indications for use	The EasyOne Filter is intended to be used in combination with NDD breathing mouthpieces to reduce bacteria, viruses and other particulates from the patient's exhaled air while performing flow measurements, such as spirometry tests. The EasyOne Filter is a single-use device and intended for single-patient use only.	The VBMax filter is a disposable, single-patient session filter for spirometric and pulmonary function testing. The VBMax filter is designed to prevent bacterial/viral contamination from entering the pulmonary function equipment. The filter is to be used with children and adults subjects, but it is not indicated for use with neonatal subjects. It is to be used under the direction of a physician.	Model 2800 is indicated for use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment. Single patient use	Same
Contraindications	None	None	None	Same
Single patient use	Yes	Yes	Yes	Same
Intended population	Adults and children over age of 4 years (users of ndd pulmonary lung function testing devices).	Any patient except neonates	Any patient	Similar
Prescription use	Yes	Yes	Yes	Same
Models	EasyOne Filter SP EasyOne Filter FT	VBMax PFT Filter	Model 2800	Different
Materials	Housing: styrene acrylonitrile (SAN) Filter media: electrostatic	Housing: styrene acrylonitrile (SAN) Free of latex, PVC,	Housing: polystyrene Filter media:	Same as predicate, similar to

Predicate device comparison table				
Criteria	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Predicate comparison results**
	polypropylene Same filter pad as used in the primary predicate device	DEHP, BPA Filter media: electrostatic polypropylene	electrostatic polypropylene	reference device
Mouthpiece	Custom fitting to NDD mouthpieces • Spirette SP • FlowTube FT	VBMax Standard: Straight ports with a paper mouthpiece or an optional pediatric adapter VBMax E-Series: Oval-shaped mouthpiece with optional, disposable rubber mouthpiece. VBMax S-Series: Smaller mouthpiece with ridges for pediatric use or for adults with smaller aperture	Filters can be supplied with accessories, such as nose clip, mouthpiece and bite grip.	Similar
Can be used with several PFT devices	No, custom fitting to NDD mouthpieces • Spirette (SP) when used with Easy-on PC Spirometer (Reference device) • FlowTube (FT) when used with EasyOne Air Spirometer (Reference device)	Yes, fits most PFT equipment in use today Custom sizes available to fit PFT equipment	Yes, various end fittings	Different
Compact housing	Yes	Yes	Yes	Same
Weight	24 grams	38 grams	40 grams	Similar

Predicate device comparison table				
Criteria	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Predicate comparison results**
Dimensions	Ø 76.6 x 77.6 mm length (SP) Ø 76.6 x 83.0 mm length (FT)	Ø 89.7 x 89.5 mm length	Ø 97 x 93 mm length	Similar
Bacterial filtration	99.999%	99.999%	99.9999%	Same
Viral filtration	99.99%	99.99%	99.999+%	Same as predicate, similar to reference device
Dead space	48 mL EasyOne Filter SP 54 mL EasyOne Filter FT	45 mL	75 mL	Similar
Sterility	non-sterile, single use	non-sterile, single use	non-sterile, single use	Same
Shelf-life	4 years	n/a	5 years	Similar
Resistance to flow at 720 lpm per ATS standard	-	0.75 cm H2O	0.7 cm H2O	Different
Resistance to flow at 60 lpm	-	0.55 cm H2O	0.5 cm H2O	Different
Resistance to flow at 840 lpm per ATS standard	Filter SP: <1.2 cmH2O/(L/s) Filter FT: <1.4 cmH2O/(L/s)	-	-	Different

The subject device EasyOne Filter has similar indications, intended use, target populations, technological characteristics, and materials as the predicate device.

The subject and predicate/reference devices have the same fundamental design, consisting of the filter pad and housing. All three filters are intended to filter the patient's exhaled air during spirometry tests. The primary filtration mechanism of the subject and predicate/reference device prevents certain particles from passing through the filter to the other side and have the same bacterial and viral filter efficiency. The filter pad used in the EasyOne Filter is the same as used in the primary predicate device. The dead space and resistance of all three filters is withing the ATS Standardization of Spirometry recommendation. The filters are made of similar materials and are all provided non-sterile and are intended for single use and single patient use only.

The EasyOne Filter has the following different technological characteristics compared to the predicate/reference device. The EasyOne Filter is either connected to the Spirette or EasyOne FlowTube and therefore dedicated for use with NDD spirometers only. The predicate/reference device has standardized connectors and may be used with different devices. The EasyOne Filter is connected at the distal end of the spirometer, i.e. away from the patient, whereby the predicate device is connected at the patient side. The EasyOne Filter is not intended to protect the test equipment itself but to prevent transmission of bacteria and viruses from the patient's exhaled air to the ambience.

The introduction of the EasyOne Filter and use with the NDD spirometers has an impact on the overall system performance. Comparative testing has been performed with the reference devices NDD spirometers when used with or without EasyOne Filter. Based on the results, it has been confirmed that the diagnostic endpoints remain the same. Furthermore, the NDD spirometers when used with and without EasyOne Filter comply with ATS Standardization of Spirometry.

The intended uses, materials and bacterial / viral efficiency are the same. Any differences between the EasyOne Filter and the predicate do not raise questions concerning safety and effectiveness. Performance testing in accordance with applicable standards demonstrates that the EasyOne Filter is adequate for its intended use. The EasyOne Filter is therefore similar to the predicate device.

SUMMARY OF NON-CLINICAL TESTS

Test	**Purpose**	**Acceptance Criteria**	**Result**
Biocompatibility	Evaluate device's biological safety for the intended use, in accordance with ISO 10993-5, ISO 10993-10 and FDA's corresponding guidance document.	Biological Evaluation per ISO 10993-5 and ISO 10993-10	Justification for cytotoxicity, sensitization, and irritation tests based on results of ViroMax filter (K063526), same filter body and filter cap materials used for EasyOne Filter as well as VBMax filter (K000654).
	Assess if airborne particulate is emitted into the gas stream in accordance with ISO 18562	Gas path emissions of particulate matter: Measured concentrations of particulate matter ≤ 2.5 µm and ≤ 10 µm were compared to air quality guidelines in ISO 18562-2.	The minimum, maximum, and average particulate concentrations are all below acceptable limits. Exposure of the individual VOCs released are unlikely to result in toxicological effects.
	Assess if airborne VOCs are emitted from the filter into the gas stream per ISO 18562	Gas path emissions of volatile organic compounds per ISO 18562-3 Risk assessment per ISO 10993-17 and ISO 18562-1	
Filtration Efficiency	Evaluate aerosol bacterial and viral removal	Bacterial filtration 99.999% (BFE) Viral filtration 99.99% (VFE)	All results were acceptable.

Test	Purpose	Acceptance Criteria	Result
	The BFE / VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.		
Dead space	Determination of dead space According to ATS/ERS standard 2005	Dead space is within the ATS/ERS recommendation of < 300ml	Passed
Connector	Verify that the connection between EasyOne Filter and the breathing mouthpieces Spirette and EasyOne FlowTube	Mechanical force is within 6 – 55N Hold in place during forced expiration (18L/s) Resistance higher 4800hPa*s/L	Passed
(ATS) Standardization of Spirometry Compliance (System test with EasyOne Filter and reference devices)	Performance testing and comparative testing of NDD spirometers used with and without EasyOne Filter demonstrated compliance with spirometry standards ISO 26782 and ATS/ERS 2019.	Test scenario according to ISO 26782 Annex B Resistance ≤ 1.5 cm H2O/L/s at 14L/s	NDD spirometers comply with ISO 26782 when used with the optional EasyOne Filter.
Human test (System test with EasyOne Filter and reference devices)	Human subjects performed a FVL test session using NDD spirometers with and without use of the EasyOne Filter. For each subject, the difference between the test session with and without filter were calculated for the following parameters: FVC, FIVC, FEV1, PEF According to ATS/ERS standard 1994	FVC & FIVC: 6% or 200 ml whichever is greater FEV1: 6% or 200 ml whichever is greater PEF: 15% or 0.50 L/min whichever is greater	NDD spirometers provide the same spirometry test results when used with or without EasyOne Filter.
Calibration checks (System test with EasyOne Filter and reference devices)	Confirm that the implemented calibration check meets specifications when NDD spirometers are used with EasyOne Filter.	Pass rate > 90%	Calibration check of NDD spirometers can be performed with EasyOne Filter.

Test	Purpose	Acceptance Criteria	Result
Configuration	Configuration of NDD spirometers for use with optional EasyOne Filter	EasyOne Air firmware V1.18 or higher and EasyOne Connect V3.9.3 or higher allows setup of spirometery testing with or without EasyOne Filter.	Passed

SUMMARY OF CLINICAL AND USABILITY TESTS

Based on a clinical evaluation including literature review and the results of verification and validation activities it has been concluded that clinical investigations were not required. A summative usability study confirmed that users understand the configuration and setup of the EasyOne Filter and how to perform spirometry tests when the filter is applied.

CONCLUSION

The conclusions drawn from the nonclinical and usability tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed devices, VBMax PFT Filter (K000654).