DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 7, 2016

Ganshorn Medizin Electronic GmbH
c/o Paul Dryden
Consultant
Industriestr 6-8
Niederlaauer, 97618 DE

Re: K160116
Trade/Device Name: SpiroScout
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: September 7, 2016
Received: September 8, 2016

Dear Paul Dryden:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

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Tina Kiang, Ph.D.
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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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K160116

Device Name

SpiroScout

Indications for Use *(Describe)*

The Ganshorn SpiroScout is intended for prescription use only to conduct simple diagnostic spirometry testing of adults and pediatric patients over 5 years old, in general practice and specialty physician, industrial and hospital settings.

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

XX 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
October 6, 2016

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Proprietary or Trade Name: SpiroScout

Common/Usual Name: Diagnostic Spirometer

Classification Name: Diagnostic Spirometer
BZG, Class II, 21 CFR 868.1840

Predicate Device: ndd Medical Technology – EasyOne 510(k) K993921

Device Description:

The SpiroScout is an electronic measurement device intended to be used for measurement of lung function (determination of the respiratory flows and volume) parameters. It enables the determination of the following parameters.

Spirometry
Inspiratory and expiratory vital capacity (VC)
Inspiratory and expiratory subdivisions

Flow/Volume
The measurement of the flow/volume curve enables the determination of the dynamic lung volumes. FEV1 value (forced expiratory volume within the first second of exhalation).

Maximum Voluntary Ventilation MVV
The respiratory limit value indicates the respired volume per minute during maximally forced respiration. The respiratory limit value is also referred to as "Maximum Voluntary Ventilation".

The SpiroScout sensor operates using two diagonally opposing ultrasound transducers that alternately send and receive ultrasonic waves. The ultrasound technology simultaneously measures the flow, temperature and humidity.

The SpiroScout is a PC-based system running the Ganshorn LFX software program. The system comprises:

- the hand-held ScoutSensor
- Base station where the sensor is stored.
- Spirette, a single use, disposable mouthpiece and flow tube

Indications for Use:
The Ganshorn SpiroScout is intended for prescription use only to conduct simple diagnostic spirometry testing of adults and pediatric patients over 5 years old, in general practice and specialty physician, industrial and hospital settings.

Patient Population:
Adult and pediatric patients 5 years of age and older

Environment of Use:
General practice and specialty physician, industrial and hospital settings

Contraindications:
None

Device Comparison
The following table compares the proposed device to the predicate ndd Medical Technology – EasyOne - K993921

Technical feature/specification	**ndd EasyOne** **K993921**	**Proposed** **Ganshorn SpiroScout**
Indications for Use	The ndd Medical Technologies EasyOne Spirometer is intended for prescription use only to conduct simple diagnostic spirometry testing of adults and pediatric patients over 4 years old, in general practice and specialty physician, industrial and hospital settings.	The Ganshorn SpiroScout is intended for prescription use only to conduct simple diagnostic spirometry testing of adults and pediatric patients over 5 years old, in general practice and specialty physician, industrial and hospital settings
Technology	Ultrasound transit-time measurement	Ultrasound transit-time measurement
Environment of use	General practice and specialty physician, industrial and hospital settings.as is the predicate.	General practice and specialty physician, industrial and hospital settings
Patient Population	EasyOne can be used for adults and pediatric patients over 4 years old	SpiroScout can be used for adults and pediatric patients over 5 years old
Accessory	Disposable spirette respiratory tube	Single use, disposable spirette respiratory tube
Energy Type	100-240 V / 50-60Hz	100 to 240 V, 50/60 Hz
Materials and type of Patient contact	Spirette Externally communicating (Indirect), Tissue and Surface Contact, Mucosa, limited exposure	Spirette Externally communicating (Indirect), Tissue and Surface Contact, Mucosa, limited exposure
Hardware components	EasyOne device Spirette USB Cradle	SpiroScout Spirette Base station
Parameters- Flow		
Flow Range	±16 l/s	±18 l/s
Flow Accuracy	Flow: ±2% or 0.020 l/s, (except PEF) PEF: ±5% or 0.200 l/s MVV: ±5% or 5 l/s	Flow: < ± 2 % or 0.03 l/s PEF: < ± 3 % or 0.15 l/s MVV: < ± 5 % or 5 l/s
Flow Resistance	approx. 0.02 cm H_2O/l/s	approx. 0.02 cmH_2O/l/s
Parameters Volume		
Volume Range	±12 liters	±10 liters

Technical feature/specification	ndd EasyOne K993921	Proposed Ganshorn SpiroScout
Volume accuracy	±2% or 0.05 liters	+/- 2 % or 0.05 liters
Parameters- Calculated		
Measurement programs (see legend below)	FVC, FVL, SVL, MVV, post testing	Slow Spirometry, Forced Spirometry, MVV
Forced Spirometry	FVC - Forced Vital Capacity (expiratory)	FVC - Forced Vital Capacity (expiratory)
Forced Spirometry	FIVC - Forced Vital Capacity (inspiratory)	FIVC - Forced Vital Capacity (inspiratory)
Forced Spirometry	FEV1 - Forced Expiratory Volume (1 s)	FEV1 - Forced Expiratory Volume (1 s)
	FEV6 - Forced Expiratory Volume (6 s)	FEV6 - Forced Expiratory Volume (6 s)
	FEV1/FVC - ratio of FEV1 to FVC	FEV1/FVC - ratio of FEV1 to FVC
	FEV1/VCmax - ratio of FEV1 to Vcmax	FEV1/VCmax - ratio of FEV1 to Vcmax
	FEV1/FEV6 - ratio of FEV1 to FEV6	FEV1/FEV6 - ratio of FEV1 to FEV6
	FEF 25 (MEF 75)	FEF 25 (MEF 75)
	FEF 50 (MEF 50)	FEF 50 (MEF 50)
	FEF 75 (MEF 25)	FEF 75 (MEF 25)
	FEF 25-75	FEF 25-75
	PEF - Peak Expiratory Flow	PEF - Peak Expiratory Flow
	PIF - Peak Inspiratory Flow	PIF - Peak Inspiratory Flow
Slow Spirometry	VT - Tidal Volume Tidal volume at rest	VT - Tidal Volume Tidal volume at rest
	ERV - Expiratory Reserve Volume	ERV - Expiratory Reserve Volume
	IRV - Inspiratory Reserve Volume	IRV - Inspiratory Reserve Volume
Slow Spirometry or Forced Spirometry	VCmax - Maximum Vital Capacity of an SVC, FVC, FVL	VCmax - Maximum Vital Capacity of an Slow or Forced Spirometry
Slow Spirometry	VC ex - Expiratory Vital Capacity of a slow spirometric test	VC ex - Expiratory Vital Capacity of a slow spirometric test
	VC in - Inspiratory Vital Capacity of a slow spirometric test	VC in - Inspiratory Vital Capacity of a slow spirometric test
	VC - Vital Capacity of a slow spirometric test	VC - Vital Capacity of a slow spirometric test
	IC - Inspiratory Capacity	IC - Inspiratory Capacity
MVV	MVV - Maximum Voluntary Ventilation	MVV - Maximum Voluntary Ventilation

Legend: The predicate ndd EasyOne and Ganshorn SpiroScout use different terms for the same programs. The equivalence of these terms is described in the table below.

	ndd Term	Ganshorn Term
Measurement Program Legend	FVC (Forced Vital Capacity), FVL (Flow Volume Loop)	Forced Spirometry
	SVL (Slow Volume Loop)	Slow Spirometry
	MVV (Maximal Volume Ventilation)	MVV (Maximal Volume Ventilation)

Summary of Performance Testing

Non-clinical

- Compliance with AAMI ANS ES 60601-1
- Compliance with IEC 60601-1-11
- Compliance with IEC 60601-1-2
- ATS (2005)

Biocompatibility:
No Biocompatibility testing was done. The only patient contacting part is the Spirette that was purchased in the final finished form from the manufacturer of the Spirette of the predicate device ndd EasyOne 510(k) K993921.

Per G95-1 and ISO 10993-1:2009, this component is considered as:

- External Communicating (Indirect gas pathway)
- Tissue / Bone / Dentin communicating
- Duration of Use – limited (<24 hours)

And

- Surface Contact
- Mucosal membrane
- Duration of Use – limited (< 24 hours)

Animal
No animal testing was performed

Clinical:
No clinical testing was performed

Comparison to Predicate Devices:
Indications for Use
As in **Comparison of Indications For Use** above, we conclude that the indications for use for the SpiroScout and the predicate are substantially equivalent.

Prescriptive – The SpiroScout and predicate are prescription devices.

Design and Technology – As above design and technology are substantially equivalent to the predicate.

Performance and Specifications –A**s** above the performance and specifications are substantially equivalent to the predicate.

Compliance with Standards – The SpiroScout complies with the currently recognized safety and EMC standards (AAMI ANSI ES 60601-1, IEC 60601-1-2). The predicate complied with IEC 601-1.

Patient Population – The SpiroScout and predicate are indicated for pediatric and adult patients.

Environment of Use – The SpiroScout is for use in general practice and specialty physician, industrial and hospital settings.as is the predicate.

Differences: There are some differences:

- Patient population is 5 and up vs. 4 yo and up
    - This has been changed based upon FDA request
- Difference in flow ranges where the proposed device has a high flow range which is consistent with the recommendations of ATS spirometer designs

The differences between the proposed device and the predicate device do not raise any new safety and efficacy concerns.

Substantial Equivalence Conclusion

Based upon the performance testing and comparison to the legally marketed predicate devices for indications for use, technology, and performance we believe we have demonstrated that the SpiroScout is substantially equivalent in safety and effectiveness to the predicate devices.