September 10, 2019

Welch Allyn, Inc.
Megan Pellenz
Regulatory Engineer
7865 North 86th St.
Milwaukee, Wisconsin 53224

Re: K191013
Trade/Device Name: Welch Allyn® Diagnostic Cardiology Suite™ 2.X.X with Spirometry option
901128 CARDIOPULMONARY ECG SYSTEM
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG, DPS
Dated: August 22, 2019
Received: August 23, 2019

Dear Megan Pellenz:

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, Ph.D.
Assistant Director (Acting)
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)*
K191013

Device Name
Welch Allyn® Diagnostic Cardiology Suite™ 2.X.X with Spirometry option
901128 CARDIOPULMONARY ECG SYSTEM

Indications for Use *(Describe)*
The Welch Allyn® Diagnostic Cardiology Suite™ is a prescription device intended for use by physicians, other licensed health care practitioners, and trained personnel who are acting on the orders of a physician. Welch Allyn Diagnostic Cardiology Suite is intended for use in medical clinics, physician offices and hospital settings to acquire, analyze, display, transmit and print certain physiological signals identified below and provide the data for consideration by a physician.
Welch Allyn Diagnostic Cardiology Suite utilizes a software platform to support 12-lead diagnostic resting ECG and diagnostic Spirometry applications and is designed to operate within the inherent capabilities of an off-the-shelf laptop or PC Windows operating system. Welch Allyn Diagnostic Cardiology Suite also provides functions related to patient data management including communication with electronic medical records systems. Welch Allyn Diagnostic Cardiology Suite Resting ECG's are intended to be taken with the patient in the supine position and offer VERITAS™ resting ECG algorithm to generate measurements and advisory statements for review and interpretation by the physician.
Welch Allyn Diagnostic Cardiology Suite is not intended to be used as a physiological vital signs monitor, not intended to be used in a mobile medical environment (e.g. ambulance, helicopter), in magnetic resonance (MR) environments, in operating theaters, nor in conjunction with high frequency surgical equipment.

Indications for Welch Allyn Diagnostic Cardiology Suite ECG range from routine screening of cardiac health in the physician office environment to directed diagnostic differentiation in a hospital cardiology department. Welch Allyn Diagnostic Cardiology Suite ECG is indicated for patients of all ages.

Welch Allyn Diagnostic Cardiology Suite Spirometry is indicated for pulmonary function testing, providing forced expiratory flow-volume and time measurements. The device is intended to be a general assessment tool assisting the clinician in the diagnosis of pulmonary function. These devices are commonly used on patients with occupational exposure to dust or chemicals; presenting with symptoms such as chronic cough, shortness of breath and wheezing; disorders such as interstitial lung disease, bronchitis, asthma, and COPD; or other patients where the clinician determines these pulmonary function measurements are needed. Welch Allyn Diagnostic Cardiology Suite with Spirometry is indicated for adult and pediatric patients age 6 years and older and should only be used with patients able to understand the instructions for performing the test.

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.

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Traditional 510(k)
Welch Allyn® Diagnostic Cardiology Suite™

510(k) SUMMARY
[As described in 21 CFR 807.92]

Submitted by Manufacturer: Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153 USA

Establishment Registration: 2183461

Primary Contact Person: Megan Pellenz, Regulatory Affairs Engineer

Secondary Contact Person: Mark Elliott, Quality Assurance Director, QMR

Date Updated: September 9th, 2019

Device Trade Name: Welch Allyn® Diagnostic Cardiology Suite™ 2.X.X with Spirometry option
901128 CARDIOPULMONARY ECG SYSTEM

Common Name: Diagnostic Spirometer

Regulation Number: 868.1840

Device Class: II

Product Code: BZG

Secondary Product code, and Regulation: DPS, 870.2340

Predicate Device: Welch Allyn CardioPerfect® Workstation Software™ (CPWS)
901047 CARDIOPULMONAY ECG SYSTEM (K082478)

Reference Device: Welch Allyn® RScribe™ (K120865)
901127 ELECTROCARDIOGRAPH

Background

The Welch Allyn® Diagnostic Cardiology Suite™ is a modification to Welch Allyn's current legally marketed RScribe cleared by FDA under K120865 and since branded "Connex Cardio". Welch Allyn's interpretation of when to submit a 510(k) for a change to an existing device and our planned device modification, the addition of indications for diagnostic spirometry, led us to the determination that the

RScribe/Connex Cardio is being significantly modified and therefore this 510(k) submission is appropriate.

Indications for Use

The Welch Allyn® Diagnostic Cardiology Suite™ is a prescription device intended for use by physicians, other licensed health care practitioners, and trained personnel who are acting on the orders of a physician. Welch Allyn Diagnostic Cardiology Suite is intended for use in medical clinics, physician offices and hospital settings to acquire, analyze, display, transmit and print certain physiological signals identified below and provide the data for consideration by a physician.

Welch Allyn Diagnostic Cardiology Suite utilizes a software platform to support 12-lead diagnostic resting ECG and diagnostic Spirometry applications and is designed to operate within the inherent capabilities of an off-the-shelf laptop or PC Windows operating system. Welch Allyn Diagnostic Cardiology Suite also provides functions related to patient data management including communication with electronic medical records systems. Welch Allyn Diagnostic Cardiology Suite Resting ECG's are intended to be taken with the patient in the supine position and offer VERITAS™ resting ECG algorithm to generate measurements and advisory statements for review and interpretation by the physician.

Welch Allyn Diagnostic Cardiology Suite is not intended to be used as a physiological vital signs monitor, not intended to be used in a mobile medical environment (e.g. ambulance, helicopter), in magnetic resonance (MR) environments, in operating theaters, nor in conjunction with high frequency surgical equipment.

Indications for Welch Allyn Diagnostic Cardiology Suite ECG range from routine screening of cardiac health in the physician office environment to directed diagnostic differentiation in a hospital cardiology department. Welch Allyn Diagnostic Cardiology Suite ECG is indicated for patients of all ages. There are no known contraindications for resting ECG.

Welch Allyn Diagnostic Cardiology Suite Spirometry is indicated for pulmonary function testing, providing forced expiratory flow-volume and time measurements. The device is intended to be a general assessment tool assisting the clinician in the diagnosis of pulmonary function. These devices are commonly used on patients with occupational exposure to dust or chemicals; presenting with symptoms such as chronic cough, shortness of breath and wheezing; disorders such as interstitial lung disease, bronchitis, asthma, and

COPD; or other patients where the clinician determines these pulmonary function measurements are needed. Welch Allyn Diagnostic Cardiology Suite with Spirometry is indicated for adult and pediatric patients age 6 years and older and should only be used with patients able to understand the instructions for performing the test.

Contraindications for diagnostic spirometry:

- hemoptysis of unknown origin (forced expiratory maneuver may aggravate the underlying condition)
- pneumothorax
- unstable cardiovascular status (forced expiratory maneuver may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus
- thoracic, abdominal, or cerebral aneurysms (danger of rupture due to increased thoracic pressure)
- Recent eye surgery (e.g., cataract);
- presence of an acute disease process that might interfere with test performance (e.g., nausea, vomiting)
  Recent surgery of thorax or abdomen.

Technological Characteristics

The Welch Allyn Diagnostic Cardiology Suite is a PC-based software device. **Section 16** details the software technology including its requirements, architecture, detailed design, development environment, verification and validation and lifecycle management plan. Medical device software development and management is characterized in IEC 62304 *Medical device software – Software life cycle processes*.

The technology of the hardware accessories are:

- For diagnostic ECG, the technology involves applying surface electrodes to the patient's skin to obtain signals of the heart's electrical activity. The electrical signals are then amplified, analyzed (VERITAS algorithms) and displayed on Welch Allyn Diagnostic Cardiology Suite ECG module user interface. Clinical Users can evaluate these ECGs, store them, save them or send them via the technological characteristics provided by the Welch Allyn Diagnostic Cardiology Suite. The diagnostic ECG technology is characterized in IEC 60601-2-25 *Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs*.
  The Welch Allyn RScribe K120865 utilizes the same VERITAS algorithms as Welch Allyn Diagnostic Cardiology Suite ECG and therefore is being cited herein as a reference device.

- For diagnostic Spirometry, a pneumotach air flow sensor obtains signals of a patient's forced expiratory breathing maneuvers, called "efforts", that are then analyzed against norms contained within Welch Allyn Diagnostic Cardiology Suite Spirometry module. Patient breathing efforts are

displayed on the Welch Allyn Diagnostic Cardiology Suite Spirometry user interface. Clinical Users can evaluate these Spirometry efforts, store them, save them or send them via the technological characteristics provided by the Welch Allyn Diagnostic Cardiology Suite. The diagnostic Spirometry technology is characterized in ISO 26782 *Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans* and follows ATS 2005 *Standardization of Spirometry* guidelines.

Device Comparison

It is of the opinion of Welch Allyn, Inc. that Welch Allyn Diagnostic Cardiology Suite is substantially equivalent to the predicate device, Welch Allyn CardioPerfect Workstation Software (K082478) as they share similar fundamental technical characteristics, intended use including indications for use, target population and use environment, detailed in the device comparison table below. The Welch Allyn® RScribe™ K120865 utilizes the same VERITAS algorithms as Welch Allyn Diagnostic Cardiology Suite ECG and therefore is presented as a Reference device.

Characteristic	Reference Device	Subject Device	Predicate Device
Trade Name	Welch Allyn® RScribe™ K120865	Welch Allyn® Diagnostic Cardiology Suite™	Welch Allyn® CardioPerfect Workstation Software™ (CPWS) V1.6.2 K082478
Model Identifier	901127 ELECTROCARDIOGRAPH	901128 CARDIOPULMONARY ECG SYSTEM	901047 CARDIOPULMONARY ECG SYSTEM
Manufacturer	Welch Allyn, Inc.	Welch Allyn, Inc.	Welch Allyn, Inc.
510(k) Number	K120865		K082478
Product Code	DPS	BZG	BZG
Classification Name	Electrocardiograph, Class II	Diagnostic Spirometer, Class II	Diagnostic Spirometer, Class II
Regulation Number	21 CFR 870.2340	21 CFR 868.1840	21 CFR 868.1840
Indications for Use	The RScribe Electrocardiograph is a multi-channel electrocardiograph product used for acquiring, analyzing, displaying and printing resting ECG's. The RScribe is a 12-channel diagnostic electrocardiograph intended for recording and printing ECG's of adult and pediatric patients. The acquired ECG will be displayed for quality check purpose, analyzed using the Mortara VERITAS resting interpretation, optionally printed, stored and/or transmitted to a ECG Management System or Hospital Information System. The device is not intended to be used as a vital signs physiological monitor. It is a system comprised of a Mortara ECG amplifier (Wireless Acquisition Module [WAM] or AM12 Patient Cable) and an off-the-shelf personal computer with Mortara software application that allows clinicians to collect ECGs on patients during	The Welch Allyn® Diagnostic Cardiology Suite™ is a prescription device intended for use by physicians, other licensed health care practitioners, and trained personnel who are acting on the orders of a physician. Welch Allyn Diagnostic Cardiology Suite is intended for use in medical clinics, physician offices and hospital settings to acquire, analyze, display, transmit and print certain physiological signals identified below and provide the data for consideration by a physician. Welch Allyn Diagnostic Cardiology Suite utilizes a software platform to support 12-lead diagnostic resting ECG and diagnostic Spirometry applications and is designed to operate within the inherent capabilities of an off-the-shelf laptop or PC Windows operating system. Welch Allyn Diagnostic Cardiology Suite also provides functions related to patient data management including communication with electronic medical	The Welch Allyn® CardioPerfect Workstation Software™ (CPWS) and associated accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals, as identified below, for the purpose of assisting the clinician in the diagnosis and monitoring of various diseases and/or treatment regimens. The CardioPerfect Workstation software also provides non-diagnostic functions such as patient management, data security, search tools for patient and/or test records and support for exporting data to Electronic Medical Record systems. The CardioPerfect Workstation Software and associated accessories are intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients as included in the cleared

Characteristic	Reference Device	Subject Device	Predicate Device
	routine visits. The patient populations for which the device will be used may be healthy or diseased of any age. ECG's are taken with the patient in the supine position. The RScribe is intended to be used by a licensed health care practitioner in a hospital, medical clinic and offices of any size, including Clinical Research Organizations. The RScribe electrocardiograph is a non-invasive prescription device. • The device is indicated for use to acquire, analyze, display, transmit and print electrocardiograms. • The device is indicated for use to provide interpretation of the data for consideration by a physician. • The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. • The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data. • The device is indicated for use on adult and pediatric populations. • The device is not intended to be used as a vital signs physiological monitor. • The device is not designed for out of hospital transport. • The device is not designed for	records systems. Welch Allyn Diagnostic Cardiology Suite Resting ECG's are intended to be taken with the patient in the supine position and offer VERITAS™ resting ECG algorithm to generate measurements and advisory statements for review and interpretation by the physician. Welch Allyn Diagnostic Cardiology Suite is not intended to be used as a physiological vital signs monitor, not intended to be used in a mobile medical environment (e.g. ambulance, helicopter), in magnetic resonance (MR) environments, in operating theaters, nor in conjunction with high frequency surgical equipment. Indications for Welch Allyn Diagnostic Cardiology Suite ECG range from routine screening of cardiac health in the physician office environment to directed diagnostic differentiation in a hospital cardiology department. Welch Allyn Diagnostic Cardiology Suite ECG is indicated for patients of all ages. Welch Allyn Diagnostic Cardiology Suite Spirometry is indicated for pulmonary function testing, providing forced expiratory flow-volume and time measurements. The device is intended to be a general assessment tool assisting the clinician in the diagnosis of pulmonary function. These devices are commonly used on patients with occupational exposure to dust or chemicals; presenting with symptoms such as chronic cough, shortness of breath and wheezing; disorders such as interstitial lung disease, bronchitis, asthma, and COPD; or other patients	indications for use listed below, subject to any specific contraindications identified below. Electrocardiograph – Indications for Use Indications for electrocardiography range from routine screening of cardiac health in the physician office environment to directed diagnostic differentiation in a hospital cardiology department. Spirometry – Indications for Use Indications for Spirometry include, but are not limited to, the following: • Shortness of breath • Chronic cough • Occupational exposure to dust or chemicals • Assist in the diagnosis of Bronchitis • Assist in the diagnosis of Asthma • Wheezing • Assist in the monitoring of bronchodilator Ambulatory Blood Pressure – Indications for Use Indications for ambulatory blood pressure measurement (as listed in Journal of Hypertension 2003, 21:821-848, E. O'Brien et. at.) include, but are not limited to, the following: • Suspected "white coat" hypertension • Suspected nocturnal hypertension • To establish dipper status • Resistant hypertension • Elderly patient

Characteristic	Reference Device	Subject Device	Predicate Device
	use in highly invasive environments, such as an operating theatre.	where the clinician determines these pulmonary function measurements are needed. Welch Allyn Diagnostic Cardiology Suite with Spirometry is indicated for adult and pediatric patients age 6 years and older and should only be used with patients able to understand the instructions for performing the test.	• To monitor antihypertensive drug treatment • Type 1 diabetes • Hypertension of pregnancy • Evaluations of hypotension • Autonomic failure • Masked hypertension

Non-clinical Performance Data
Non-clinical data was utilized in this submission. The non-clinical standards and tests that were submitted, referenced or relied upon to support a determination of substantial equivalence are:

ISO 14971 Medical devices - Application of risk management to medical devices (2007)

ANSI/AAMI ES 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (2005+A1:2012)

IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

ANSI/AAMI IEC 62304 Medical device software - Software life cycle processes (2006)

IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (2015)

AAMI/ANSI HE75 Human Factors Engineering – Design of Medical Devices (2009 R2013)

IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral standard: Usability (2010+A1:2013)

IEC 60601-2-25 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs (2011)

ISO 26782 Anaesthetic and respiratory equipment -- Spirometers intended for the measurement of time forced expired volumes in humans (2009)

ATS 2005 Standardization of Spirometry

ISO 10993-1 (2009+Cor.1:2010) Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The spirometry patient-contacting materials are identical or equivalent to the materials cleared in K133428. The ECG patient-contacting materials are identical to the materials cleared in K120865.

Clinical Performance Data
No clinical studies were utilized for the purpose of showing substantial equivalence.

Conclusion
The Welch Allyn Diagnostic Cardiology Suite subject device and its predicate, the Welch Allyn CardioPerfect Workstation Software (CPWS) K082478 share the same intended use, the same modular software design, the same installation environment, the same general operating principles, the same basic technology and share similar performance claims and labeling. The Welch Allyn RScribe K120865 utilizes the same VERITAS algorithms as the subject device and has been in clinical use since 2012. Minor differences between the devices do not raise concerns of differences in safety, efficacy or intended use. Non-clinical performance tests were conducted and submitted to demonstrate that the Welch Allyn Diagnostic Cardiology Suite performs similarly to the predicate. It is Welch Allyn's opinion that the Welch Allyn Diagnostic Cardiology

Suite subject device is substantially equivalent to its predicate, the Welch Allyn CardioPerfect Workstation Software (CPWS) cleared through K082478.