DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 6, 2016

Schiller Ag
% Jim Chickering
Regulatory Affairs Manager
Zoe Medical, Inc.
460 Boston Street
Topsfield, Massachusetts 01983

Re: K152043
Trade/Device Name: Diagnostic Station Ds20
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DXN, BZG, DQA, MWI, BZQ, FLL, JKS
Dated: March 21, 2016
Received: March 29, 2016

Dear Jim Chickering:

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,

for Shawn W. Forrest -S
2016.05.06 09:06:22 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152043

Device Name
Diagnostic Station DS20

Indications for Use *(Describe)*
The Diagnostic Station DS20 is a 12-lead EGG device used for the recording, analysis and evaluation of ECG waveforms. Recordings made with the DS20 can be used as a diagnostic aid for heart function and heart conditions.

The DS20 also measures the following patient vital information to further aid in patient assessment: pulmonary lung function (spirometry), blood pressure, functional oxygen saturation of arterial hemoglobin (SpO2), carboxyhemoglobin saturation (SpCO), respiration, temperature, and weight.

The DS20 is intended for data collection only. It is not intended for continuous monitoring use and does not provide an alarm function.

The DS20 is indicated for use in hospital and clinic settings, on adult and pediatric patients.

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

I. SUBMITTER

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Contact Person: Zhenrong Yu MD, PhD
Date Prepared: June 30, 2015

II. DEVICE

Name of Device: Diagnostic Station DS20

Common Name: Electrocardiograph, Diagnostic Spirometer, Vital Signs Device

Classification Product Code:

DPS – Electrocardiograph (21 CFR 870.2340)

Secondary Product Codes:

DXN – NIBP Measurement System (21 CFR 870.1130)
BZG – Diagnostic Spirometer (21 CFR 870.1840)
DQA – Oximeter (21 CFR 870.2700)
MWI – Physiological Patient Monitor (21 CFR 870.2300)
BZQ – Breathing Frequency Monitor (21 CFR 868.2375)
FLL – Clinical Electronic Thermometer (21 CFR 880.2910)
JKS – Carbon Monoxide Test System (21 CFR 862.3220)

Regulatory Class: II

III. PREDICATE DEVICE

The primary predicate device is the SCHILLER Cardiovit AT-10 Plus.

Secondary predicate devices are cited for their use of the same physiological parameter OEM module as the subject device.

No reference devices were used in this submission.

Predicate Scope	Predicate Device	510(k)	Classification
Primary Predicate (12-lead ECG Electrocardiograph with Spirometry option)	SCHILLER Cardiovit AT-10 Plus	K050686	DPS
OEM Module Non-invasive Blood Pressure (NIBP)	SCHILLER BP-200 Plus	K063814	DXN
OEM Module Pulse Oximetry (SpO_2)	Covidien Respiratory Patient Monitor	K130320	DQA
OEM Module Pulse Oximetry (SpO_2, SpCO)	Masimo Radical 7	K110028	DQA, JKS
OEM Module 5-lead ECG and Respiration	Zoe Medical Nightingale Monitoring System	K130740	MWI
OEM Module Temperature	Exergen Temporal Scanner Thermometer	K011291	FLL

IV. DEVICE DESCRIPTION

The Diagnostic Station DS20 is a 12-lead EGG (Electrocardiograph) device used for the recording, analysis and evaluation of ECG waveforms. It also measures the following patient vital information to further aid in patient assessment: pulmonary lung function (spirometry), blood pressure, functional oxygen saturation of arterial hemoglobin (SpO_2), carboxyhemoglobin saturation (SpCO), respiration, temperature and weight. It also supports a 5-lead ECG measurement of heart rate when 12-lead ECG analysis is not needed.

The DS20 does not provide a patient monitoring capability with alarm annunciation.

The DS20 has a color display. It accepts user input via a touch panel, barcode scanner or keyboard. It can generate a variety of reports that can be viewed on the display or printed on a strip chart recorder or laser printer.

The DS20 is mains- or battery-powered and uses sensors that come in contact with the patient.

The DS20 is intended to function in the patient vicinity alongside other medical devices. It can operate as a stand-alone device or can be connected to the SCHILLER SEMA3 Data Management System via Ethernet (land-line or WiFi) in order to store reports and retrieve work orders for a given patient.

V. INDICATIONS FOR USE

The Diagnostic Station DS20 is a 12-lead EGG device used for the recording, analysis and evaluation of ECG waveforms. Recordings made with the DS20 can be used as a diagnostic aid for heart function and heart conditions.

The DS20 also measures the following patient vital information to further aid in patient assessment: pulmonary lung function (spirometry), blood pressure, functional oxygen saturation of arterial hemoglobin (SpO_2), carboxyhemoglobin saturation (SpCO), respiration, temperature, and weight.

The DS20 is intended for data collection only. It is not intended for continuous monitoring use and does not provide an alarm function.

The DS20 is indicated for use in hospital and clinic settings, on adult and pediatric patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE

The subject device has the same technological characteristics and intended use as the primary predicate.

Differences between the subject device and primary predicate include the use of:

- a larger display
- a touch panel instead of fixed keys for user input
- an external laser printer instead of an integrated thermal printer for reports
- newer battery technology
- more readily available electrical components (e.g., microcontrollers, memory chips)

Additional physiological parameters have been added to the subject device, which are provided by OEM modules. These OEM modules are used in the cited secondary predicates.

These differences do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

Electrical safety, essential performance and electromagnetic compatibility (EMC) testing

The Diagnostic Station DS20 was successfully tested to the following regulatory standards:

Standard	Standard Title
IEC 60601-1:2005 + CORR 1 (2006) + CORR 2 (2007)	3rd Edition, Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
AAMI ES 60601-1:2005	3rd Edition, Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
ANSI/AAMI SP10:2002, Am1:2003	Manual, electronic and automated sphygmomanometers
IEC 60601-1-2:2007	Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
IEC 60601-1-4:2000	Medical Electrical Equipment, Part 1-4: General Requirements for basic safety and essential performance – Collateral Standard: Programmable electrical medical systems
IEC 60601-1-6:2010	Medical Electrical Equipment, Part 1-6: General Requirements for basic safety and essential performance – Collateral Standard: Usability
IEC 60601-2-25:2011	Medical Electrical Equipment, Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27:2011	Medical Electrical Equipment, Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
IEC 80601-2-30:2009	Medical Electrical Equipment, Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
ISO 80601-2-49:2011	Medical Electrical Equipment, Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-56:2009	Medical Electrical Equipment, Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011	Medical Electrical Equipment, Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 62366:2007 + A1:2014	Medical Devices - Application of usability engineering to medical devices
IEC 62304:2006	Medical Device Software - Software life cycle processes

Software Verification and Validation Testing

Software verification and validation testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered as a "moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient through incorrect or delayed information or through the action of a care provider.

VIII. CONCLUSIONS

Based upon a comparison of devices and performance testing results, the SCHILLER Diagnostic Station DS20 is substantially equivalent to the predicate devices.