DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 19, 2017

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

Re: K170182
Trade/Device Name: CARDIOVIT FT-1
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 8, 2017
Received: June 12, 2017

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,

for 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)*
K170182

Device Name
CARDIOVIT FT-1

Indications for Use *(Describe)*
The CARDIOVIT FT-1 is a 12-channel ECG unit used for the recording, analysis, viewing, storage and transmission of ECG waveforms.

The CARDIOVIT FT-1 is designed for indoor use and can be used for all patient populations.

The CARDIOVIT FT-1 is used to diagnose cardiac abnormalities, and detect acute myocardial ischemia and infarctions in chest pain patients.

The CARDIOVIT FT-1 is intended for use in hospitals, cardiology units, out-patient clinical units and general physician's offices.

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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SCHILLER
The Art of Diagnostics

510(k) Summary

1. General information

Submitter	
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Contact Person:	Zhenrong Yu, MD, Ph.D. Vice President Regulatory Affairs and Quality Assurance
Date Prepared:	May 22, 2017

Device	
Device Trade Name	CARDIOVIT FT-1
Manufacturer	Schiller AG Altgasse 68 CH-6341 Baar Switzerland
Common Name:	Electrocardiograph
Product Code:	DPS – Electrocardiograph (21 CFR 870.2340)
Regulatory Class	II

2. Predicate Device

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

A secondary predicate device is cited for its use of the same electrocardiograph physiological parameter technology as the subject device.

No reference devices were used in this submission.

Predicate Scope	**Predicate Device**	**510(k)**	**Classification**
Primary Predicate	SCHILLER CARDIOVIT	K050686	DPS

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Predicate Scope	Predicate Device	510(k)	Classification
	AT-10 Plus		
Secondary Predicate (electrocardiograph physiological parameter technology)	SCHILLER Diagnostic Station DS20	K152043	DPS

3. Device Description

The CARDIOVIT FT-1 is a 12-lead ECG (Electrocardiograph) device used in the recording, analysis, viewing, storage and transmission of ECG waveforms.

The CARDIOVIT FT-1 does not provide a patient monitoring capability with alarm annunciation.

The CARDIOVIT FT-1 has a color display. It accepts user input via a touch panel or barcode scanner. It can generate a variety of reports that can be viewed on the display or printed on a strip chart recorder that is built into the device.

The CARDIOVIT FT-1 is mains- or battery- powered and uses sensors that come in contact with the patient.

The CARDIOVIT FT-1 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.

4. Indication For Use

The CARDIOVIT FT-1 is a 12-channel ECG unit used for the recording, analysis, viewing, storage and transmission of ECG waveforms.

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The CARDIOVIT FT-1 is used to diagnose cardiac abnormalities, and detect acute myocardial ischemia and infarctions in chest pain patients.

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The CARDIOVIT FT-1 is intended for use in hospitals, cardiology units, out-patient clinical units and general physician's offices.

5. Comparison of Technological Characteristics with Predicate

The subject device has the same device characteristics and intended use as the primary predicate device. The subject device has exactly the same electrocardiograph physiological parameter technology as the secondary predicate device.

At a high level, the subject and predicate devise are based on the following same technological elements:

- 12 lead ECG electrocardiographs
- with data analysis
- without alarm annunciation

The following technological differences, corresponding to technological upgrades, exist between the subject and the predicate device:

- Slimmer and lighter design
- Virtual keyboard and keys instead of an integrated keyboard
- Higher display resolution
- Increased Database Storage
- Modern network technology (including WLAN)
- Wider range of operating and storage conditions
- Use of a more readily available electrical components (e.g., microcontrollers, memory chips)
- Use of an external (rather than internal) medical-grade power supply
- Use of a newer battery technology

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

6. Performance Data

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

The CARDIOVIT FT-1 was successfully tested to the following regulatory standards:

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Standard	Standard Title
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	3rd Edition, Medical Electrical Equipment, Part 1: 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 Compatibility
IEC 60601-1-6 : 2010 (Third Edition) + A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-25:2011	2nd Edition. Medical Electrical Equipment, Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 62366:2007 (First Edition) + A1:2014	Medical Devices - Application of usability engineering to medical devices
IEC 62304:2006	Medical Device Software - Software life cycle processes

6.2. 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.

7. Conclusions

Based upon a comparison of devices and performance testing results, the SCHILLER CARDIOVIT FT-1 is substantially equivalent to the predicate devices.