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

January 13, 2017

CEFLA S.C.
% Maurizio Pantaleoni
CEO
Isemed Srl
Via Argentina Altobelli Bonetti 3A
Imola, BO 40026
ITALY

Re: K163519
Trade/Device Name: RX DC
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: November 24, 2016
Received: December 15, 2016

Dear Maurizio Pantaleoni:

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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K163519

Device Name
RXDC

Indications for Use *(Describe)*
RX DC x-ray unit is designed for use in the dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) Summary is being submitted as required **by** 21 CFR 807.92.

1. General Information

Submitter :

CEFLA S.C.
Via Selice Prov.le 23/a
Imola, BO 40026 ITALY
Tel. +39 0542 653441
Fax +39 0542 653607

Consultant/ Contact:

Maurizio Pantaleoni
ISEMED srl
Via Altobelli Bonetti 3/a
Imola, BO 40026 ITALY
Mob. +39 348 4435155
Tel. +39 0542 683803
Fax +39 0542 698456
Email: regulatory@isemed.eu

Summary Prepared Date: November 24, 2016

2. Names

Device Name:	RX DC
Common Name:	Unit, X-Ray, Extraoral with timer
Regulation Name:	Extraoral Source X-Ray System
Product Code:	EHD
Classification:	21CFR 872.1800; Class II

3. Predicate Devices

The RX DC, in the new 65/70 kV version, is substantially equivalent to the following device:

Applicant	Device name	510(k) Number
CEFLA S.C.	RXDC	K080076
VIVI S.r.l.	VIVI Ergon-X HF	K120318

4. Device Description

The subject device RX DC, in the new 65/70 kV version, is an extraoral source dental X-ray system intended for intraoral imaging. The subject device is a device comprises a double mobile and articulate support arm. At the opposite ends of the arm are located, respectively:

- A control unit equipped with wall plate, extension arm and wired/wireless control device;
- A tube head with x-ray tube;

X-rays are produced using the high frequency and constant potential generators with a built in round collimator with the high frequency (HF) technology, X-ray emission at 70 kV and 8 mA (maximum power), and x-ray unit automatically calculates the best exposure time (from 0.02 s to 1.00 s) based on the selected tooth and patient size, as well as an adjustable arm allows for easy positioning. The system can be used either with conventional film or a digital imaging system.
RX DC, 65/70 kV version, is manufactured by CEFLA S.C. and available in several versions, and it can be sold under different brands and commercial names for commercial needs, as well as with different type of installation, and also different types of maximum anode voltage (65 kV or 70 kV).
To identify the different variants of the RX DC product, CEFLA S.C. designed a reference system to identify any variant via the REF code.

5. Indications for Use

RX DC x-ray unit is designed for use in the dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.

6. Comparison of technological characteristics with the predicate device

The RX DC, in the new 65/70 kV version, represents a development of the cleared RX DC (K080076), which has a fixed x-ray tube potential 60kV. In addition, concerning the maximum voltage of 70KV, this parameter is identical to that of the other predicate device K120318.

All relevant characteristics of the subject device are side-by-side compared with those of the predicate devices in the Comparison table.

	Subject Device	**Predicate Devices**	
	CEFLA S.C. **RX DC**	**CEFLA S.C.** **RX DC** **K 080076**	**VIVI** **Vivi Ergon- X HF** **K 120318**
General Features			
Classification	II	II	II
Product Code	EHD	EHD	EHD
Intended use	This x-ray unit is designed for use in the dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.	This x-ray unit is designed for use in the dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.	Ergon-X-HF is an extraoral X-ray source system intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaws, and oral structures.
Principle of use	X-Ray Tube	X-Ray Tube	X-Ray Tube
Mechanical Features			
Installation configuration	Wall-mounted standard version Stand mobile version	Wall-mounted standard version	Wall-mounted standard version Fixed floor Stand Stand mobile version
X-ray emission control	Wired control Wireless Remote control	Remote control	Wired control Wireless remote control
Extension arm	90 cm (standard) 40 cm (optional) 60 cm (optional)	90 cm (standard) 40 cm (optional) 60 cm (optional)	30 cm (standard) 60 cm (optional) 80 cm (optional)
Radiological characteristics			
HV generator	High frequency Constant potential	High frequency Constant potential	High Frequency Constant potential
Anode material	Tungsten	Tungsten	Tungsten
Tube Voltage (KV)	60, 63, 65 kV 60,65, 70 kV	60 kV	60, 65 or 70 kV
Tube current (mA)	6, 7 mA @65kV 4, 8 mA @ 70 kV	7mA 3.5mA	7 mA
Exposure time	0.02s-1s (R 20 steps)	0.01sec. – 1sec. (in R20 steps)	0.01 - 2.0 sec
X-ray tube & anode angle	• From 12.5° to 16°	12.5°	19°
Focal spot size	• 0.4mm / 0.7mm	0.4mm	0.5mm
Leakage radiation	< 0.25 mGy/h (@ 1 m)	< 0.25 mGy/h (@ 1 m)	< 0.25 mGy/h (@ 1 m)

Collimators			
Focus film distance	• Short round (fix): 200 mm (8'') • Long rectangular (removable): 300mm (12'') • Round (removable): 300mm (12'')	• Short round (fix): 200 mm (8'') • Long rectangular (removable): 300mm (12'')	200 mm
Diameter of X-ray beam cone	• Short round (fix): Ø 60 mm • Long rectangular (removable): Ø 45x35mm • Round (removable): Ø 55 mm	• Short round (fix): Ø 60 mm • Long rectangular (removable): Ø 45x35mm	Ø 60 mm
Radiological parameters			
Exposure times control	Microprocessor controlled exposure times	Microprocessor controlled exposure times	Microprocessor controlled exposure times
Exposure modes	preset loading factors or Manual mode	preset loading factors	automatic exposure or manual exposure
Selectable parameter	Patient type, anatomical position,	Patient type, anatomical position,	Patient size, anatomical position, film type
Patient type	Adult-child	Adult –child	-
Tooth type	Molar (upper and lower) Premolars (upper and lower) Incisors/canines (upper and lower) Bite wing	Molar (upper and lower) Premolars (upper and lower) Incisors/canines (upper and lower) Bite wing	Molar (upper and lower) Premolars (upper and lower) Incisors/canines (upper and lower) Bite wing
Film type	Sensor or photostimulated plate	Sensor or photostimulated plate	Class E – F - D (selectable)
Standards			
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 62304	IEC 60601-1 IEC 60601-1-2 IEC 62304	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 62304

According to table above, the subject device has similar technology and features than the predicate devices K080076 and K120318, pointing out only few differences.

The differences like the highest energy available is 70 keV or the necessity to manage a wired controller together an others, together with some electronic changes introduced in the subject device, as indicated in the table, have caused the need for software changes in order to allow the firmware porting, but the two mains parts of the software, that consist of the user interface management and the control algorithms that manage the x-ray tube remained substantially the same. Finally this modification has been validated in compliance with the same standard used in the predicate device as indicated in the comparison table

Furthermore all these differences have been addressed by dedicated performance tests demonstrating that the technical differences have the equivalent results concerning the performance of the dose released during the radiographic exposition. Therefore, the subject device is able to produce comparable performances in term of emitted dose respect the correspondent dose emitted by RX DC cleared by FDA with K080076.

7. Performance Data

The following tests were performed for determination of substantial equivalence:

1) Non clinical tests performed on the subject device:

A. Safety and EMC tests conducted in compliance with the declared standards:

- IEC 60601-1:2005
- IEC 60601-1-6:2013
- IEC 62366: 2014
- IEC 60601-1-3:2013
- IEC 60601-2-65:2012
- IEC 60601-1-2:2007 (EMC)

For all consensus standards here above all requirements have been met.

B. Comparative dosimetric test:

The test purpose is to measure the air kerma emitted by the subject device and RX DC (K080076), for each combination of loading factors accordingly to patient size and anatomical shape of the tooth, in order to verify that the technical differences have the equivalent results concerning the performance of the dose released during the radiographic exposition

The test results demonstrated that RX DC, in the new 65/70 kV version, emits the same quantity of x-ray than the predicate device K080076.

8. Conclusions

In light of evidence discussed above and underlining similar technological features for these three compared devices as well as pointing out the compliance with the same safety-related standards and the similar performance as demonstrated by dedicated performance test, the subject device may be found substantially equivalent to the predicate devices K080076, and K120318.

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