March 7, 2018

GENORAY Co., Ltd.
% Mr. Chris Yoon
Business Development Manager
Genoray America Inc.
147 E. Bristol Lane
ORANGE CA 92865

Re: K172810
Trade/Device Name: PORT-X IV
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: January 9, 2018
Received: February 12, 2018

Dear Mr. Yoon:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K172810

Device Name
PORT-X IV

Indications for Use *(Describe)*
PORT-X IV is a portable X-ray system to be used by trained dentists and dental technicians as a mobile, extra oral x-ray source for producing diagnostic x-ray images using intra oral image receptors. It is intended for both adult and pediatric subjects.

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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Exhibit 5 510(k) Summary

Date of Summary Preparation: Aug. 11, 2017

1. Submitter and US Official Correspondent

Submitter : GENORAY Co., Ltd.
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Email: kaitlynn@genorayamerica.com

2. Establishment Registration Number

3005843418

3. Device Information

Trade/Device Name:	PORT-X IV
Regulation Name:	Portable X-ray System
Classification Name:	Extraoral Source X-ray System
Product Code:	EHD
Device Class:	Class II per regulation 21 CFR 872.1800

4. Predicate Device(Equivalent Legally Marketed Device)

Manufacturer:	Metabiomed, Inc.
Device Name:	REXTAR X
510(k) Number:	K132041 (Decision Date – Jul 31, 2013)
Classification:	Extraoral Source X-ray System Class II per regulation 21 CFR 872.1800

5. Description of the Device

The portable X-Ray system, PORT-X IV, is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is the X-ray equipment and uses it to diagnose the patient to

acquire images. It also includes accessories, which are battery, recharging unit and hand switch.

6. Indications for use (intended use)

PORT-X IV is a Portable X-Ray System to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.

7. Substantial equivalence chart

Name	Proposed device PORT-X IV	Predicate device REXTAR X
Manufacturer	GENORAY Co., Ltd.	Metabiomed, Inc.
510(k) No.	-	K132041
Indications for use	PORT-X IV is a portable X-ray system to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.	REXTAR X is a portable X-ray system to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray Images using Intraoral Image receptors. It is intended for both adult and pediatric subjects.
X-ray Generator	Tube Voltage : 70 kV Tube Current : 2 mA	Tube Voltage : 70 kV Tube Current : 2 mA
X-ray Controller	Exposure Time : 0.05~1.6 sec	Exposure Time : 0.01~1.30 sec
X-ray Tube	Stationary Anode	Stationary Anode
	Focus : 0.4 mm Target Angle : 12.5˚ Total Filtration : 2.2 mmAl (Inherent Filtration : 1.0 mmAl; Additional Filtration : 1.2 mmAl)	Focus : 0.4 mm Target Angle : 12˚ Total Filtration : 1.5 mmAl (Inherent Filtration : 1.0 mmAl; Additional Filtration : 0.5 mmAl)
Battery	Type : Rechargeable	Type : Rechargeable
Display	LCD panel Dispaly	LCD panel Dispaly
Dimensions and Weight	Dimension(mm):140 x 173 x 254 Weight(kg): 1.6 kg	Dimension(mm): 146 x 155 x 139 Weight(kg): 2 kg

The technical characteristics of the PORT-X IV and predicate device are similar.
However the range of the exposure time and the total filtration of X-ray tube are little different. Those differences does not affect the performance and safety. Safety, EMC and performance data demonstrated that the PORT-X IV is as safe and effective as the predicate device.

The PORT-X IV is substantially equivalent to the predicate device, REXTAR X(K132041).

8. Safety, EMC and Performance data comparison to Predicate device

- Safety, EMC and Performance Data

PORT-X IV complies with industry standards such as IEC 60601-1 Series and 21 CFR 1020.30 and 21CFR 1020.31 to minimize electrical, mechanical and radiation hazards.

· Electrical, mechanical, environmental safety and performance testing which are mentioned in the standard IEC 60601-1, IEC 60601-1-3 and IEC 60601-2-65 were performed.
· EMC testing was conducted in accordance with standard IEC 60601-1-2.
· Performance testing performed according to FDA 21 CFR 1020.30, 21 CFR 1020.31 standards, Software Validation, Clinical Evaluation. All test results were satisfactory.

- Summary of Performance Testing

The performance test for the subject device, PORT-X IV and the predicate device, REXTAR X(K132041) confirmed that the focal spot to skin distance of both devices were longer than the minimum length of 18 cm in accordance with Federal Standard (21CFR 1020.30 and 31) requirements. Also minimum HVL (half-value layer) of both devices were 1.5 mm in accordance with Federal Standard (21CFR 1020.30 and 31) requirements. Accuracy of loading factors and reproducibility of AIR KERMA for both devcies also met the essential performance requirements in accordance with IEC 60601-1 (ex. <70kVp +10%).

All the test results were satisfied and the result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate device.

9. FDA Guidance Documents Utilized

- Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use, issued December 24,2008
- Guidance for the Content of Premakret Submissions for Software Contained in Medical Devices, issued Nov 28, 2017
- Pediatric Information for X-ray Imaging Device Premarket Notifications, issued May 10, 2012
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued October 2, 2014

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, issued Jun 9, 1997.
- Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, Aug 6, 1999.

10. Conclusion

In reference to the comparison information provided in substantial equivalence chart, most of functions and electronic features are similar with predicate device. We believe that the PORT-X IV is safe and effective as predicate device, and has no new indication for use. Therefore, PORT-X IV is substantially equivalent to predicate device.