December 4, 2024

Raypia Co., Ltd
% Yolanda Smith
Consultant
Ganseo Hangang XI Tower
401 Yanhcheon-ro
Gangseo-gu, Seoul,
SOUTH KOREA

Re: K242185
Trade/Device Name: Rextar Pro
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: July 24, 2024
Received: November 5, 2024

Dear Yolanda Smith:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
See *PRA Statement below.*

Submission Number *(if known)*

K242185

Device Name

Rextar Pro

Indications for Use *(Describe)*

REXTAR PRO 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 adult 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K242185

510(k) Summary

Prepared on: 2024-11-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Raypia Co., Ltd
Applicant Address	Ganseo Hangang XI Tower 401 Yanhcheon-ro Gangseo-gu, Seoul Korea, South
Applicant Contact Telephone	888-729-9674
Applicant Contact	Mrs. Yolanda Smith
Applicant Contact Email	ysmith@fdaconsultants.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Rextar Pro
Common Name	Extraoral source x-ray system
Classification Name	Extraoral source x-ray system
Regulation Number	872.1800
Product Code(s)	EHD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K132041	REXTAR X	EHD

Device Description Summary

21 CFR 807.92(a)(4)

The REXTAR PRO is an X-ray device offering a lightweight, compact portable X-ray generator. The generator is a high frequency X-ray generator, with a high Output at 70kV / 2mA. The battery-powered device is a Ripple-free HF type of generating device.

The REXTAR PRO X-ray function is controlled by Touch Screen and Button for convenience. The handheld device features a main body (X-ray tube head), rechargeable battery (handset), charger, and charger AC/DC power supply.

REXTAR PRO uses a high-quality shielding material for shielding (using domestically produced 99.9% purity lead. The RETAR PRO minimizes the exposure of the users from X-ray scattering by adding a backscatter shield. The REXTAR PRO's uses a GRID Tube and is a specialized X-ray tube that improves the quality of the x-ray beam by controlling the flow of electrons through the GRID placed between the cathode and anode. It's application of the Focal Spot 0.2mm GRID Tube for clearer, high-quality imaging helps with the diagnosis for accurate procedures and minimizes patient radiation exposure.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

REXTAR PRO 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 adult patients.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Similar indications for use

Technological Comparison 21 CFR 807.92(a)(6)

Discussion of Technological Differences

Indications for Use

The REXTAR PRO is not indicated for pediatric patient's vs the PRO X which is indicated for pediatric patients. The REXTAR PRO labeling clearly states that it indicated for adults only and the electrical and EMC test results demonstrate that no new issues safety and effectiveness were raised.

Device Power Source

Predicate 19-VDC 3.16A

Subject device 12.6 VDC 1A

This difference does not raise any new safety issues, according to the EMC and electrical testing reports.

Charger Power

Charger – predicate 00-250 VAC, 50-60Hz 1.5A-0.75A

Charger subject - 100-240 VAC, 50/60Hz 0.13-0.26A

This difference does not raise any new safety issues, according to the EMC and electrical testing reports.

Tolerance kV and sec

Predicate – kV ± 7% – Subject device kV ±5%

Predicate – sec ±10% - Subject device sec ±5%

This difference does not raise any new safety issues, according to the EMC and quality system design verification and validation activities.

Display

• Different LCD panel

This is a design difference to accommodate smaller mobile X-ray device and does raise any new issues of safety and effectiveness.

X-ray tube – Inherent Filtration

Predicate - 1.0mmAL Eq.

Subject device – 0.5mm AL Eq.

This is a design difference to accommodate smaller design mobile X-ray device and does raise any new issues of safety and effectiveness.

X-ray tube -Addition

Predicate 0.5mmAL

Subject device – 1.0mm AL

This is a design difference to accommodate smaller design mobile X-ray device and does raise any new issues of safety and effectiveness.

Size

Predicate -146 x 155x 139mm

Subject device – 140 x 163.5 x 140mm

This is a design difference to accommodate smaller design mobile X-ray device and does raise any new issues of safety and effectiveness.

Weight

Predicate – 1.9 kg

Subject device – 1.5 kg

This is a design difference to accommodate smaller design mobile X-ray device and does raise any new issues of safety and effectiveness

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance Testing - Bench

REXTAR Pro has been tested to applicable IEC Standards and FDA Guidance documents to include:
IEC 60601-2-65: Edition 1.2 2021-05 CONSOLIDATED VERSION: Medical electrical equipment Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

IEC 60601-1 Edition 3.2 (2020)-08 CONSOLIDATED VERSION: Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic distrubances-requirements and tests

FDA software guidance: Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff

Leakage Radiation Test
To characterize the REXTAR PRO, measurements of leakage radiation were made at 15 different points to approximate a sphere around the REXTAR PRO.
Conclusion
Radiation measurements at the REXTAR PRO backplane and accessible points, it is possible to estimate the maximum dose that would be received by an operator using the REXTAR PRO. The typical whole body exposure to the operator can be estimated using the measured sum of leakage radiation level. This is at the maximum duty cycle of 60 images per hour. NCRP (National Council on Radiation Protection and Measurements) reports that a high-volume dental practice would take 300 images per week.

REXTAR PRO's radiation emitting level at operator's perspective is fairly minimum amount than NCRP requirement; occupational radiation exposure to adults working with radioactive material to 5,000 mR (50 mSv) per year.

Conclusion
The REXTAR PRO has the same indication for use and technical characteristics to the predicate device. Based on this information, we conclude that the differences between the proposed device and predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness.