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

June 8, 2017

Skanray Technologies Private Limited
% Parul Chansoria
Regulatory Consultant
ELEXES Medical Consulting Pvt. Ltd
6484, Tralee Village Dt
Dr DUBLIN, California 94568

Re: K170967
Trade/Device Name: Intraskan DC Plus
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: March 18, 2017
Received: March 31, 2017

Dear Parul Chansoria:

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

Robert A. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170967

Device Name
INTRASKAN DC PLUS

Indications for Use *(Describe)*
INTRASKAN DC PLUS is High Frequency extra oral X Ray source to be used for Intra-Oral X-Ray in Dental radiography for diagnostic purpose.

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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SECTION 7. 510(K) SUMMARY

7.1. SPONSOR

Date	JAN 19, 2017
Applicant	Skanray Technologies Private Limited, Plot # 15-17, Hebbal Industrial Area Mysore-570016, India
Contact Person	Parul Chansoria, Regulatory Consultant, Elexes
Email Id	parul@elexes.com
Phone	650-528-2445

7.2. ESTABLISHMENT REGISTRATION NUMBER

FDA establishment registration number: 3009001657

7.3. DEVICE NAME

Device Name: INTRASKAN DC PLUS
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Primary Product Code: EHD
Classification Name: Unit, X-Ray, Extra oral with Timer
Variants: Wall, Chair Mount & Floor Stand

7.4. PREDICATE DEVICE

510(k) number: K111330
Device Name: INTRASKAN DC
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Primary Product Code: EHD
Classification Name: Unit, X-Ray, Extra oral with Timer
Variants: Wall, Chair Mount & Floor Stand

7.5. PRODUCT DESCRIPTION

INTRASKAN DC PLUS is High Frequency extra oral X Ray source to be used for Intra-Oral X-Ray in Dental radiography for diagnostic purpose. The system houses two microprocessors,

one for control / supervisory functions and another for man-machine/user interface. The technology incorporates feedback circuits to ensure accuracy & reproducibility of X-Ray output.

The Intra Oral X-ray does not have provision to connect to wireless networks or LAN.

7.5.1 INTRASKAN DC PLUS CONSISTS OF THE FOLLOWING MAIN COMPONENTS:

Base Unit

Tube Housing

Beam Limiting Device-inbuilt with tube Housing
Control Console, 9.84 Ft (3 m) coiled cord.

Rotating yoke for tube housing mounting
Extension arm

Scissor arm

7.5.2 OPTIONAL COMPONENTS:

Long Cone 11.8in (300mm)

9.84 Ft (3m) coiled cord with exposure switch
Dead man switch

Remote keypad with external doorbell switch

The Power supply is regulated to provide a selectable 60 to 70 kVp in step of 1kV at a selectable tube current of 4, 5,6, 7, or 8 mA. The range of exposure time is 0.01 to 3.50 seconds (Any change in the step from the previous setting shall be as per R20 Table in Annex B of 60601-1-3) with 1:15 duty. Predefined exposure parameters kV, mA & exposure time values may be stored in, selected & operated via the operator control panel.

7.6. CHANGE DETAILS

To have common set of PWA to enable the device to work with power supply range of 100-110/230-240VAC, 60/50Hz. (ECR# 160301)

Adjustment in exposure time range and APR tables to closely align with IEC 60601-1-3, Annex B. (ECR# 160301)

To have a common console with remote keypad option and prep time reduction (ECR#140501)

Change in console firmware to set a min kV as 60kV (as per standard 60601-2-65) & min time as 10mS. (ECR# 160301)

Standardized SSD of 22CM inbuilt and 30CM with optional Cone as in the Predicate device INTRASKAN DC (K111330)

Change in Base unit aesthetic. (ECR#12081)

Total Weight of System (Including Packing carton) changed for Wall mount: approx. 49.89 kg's to approx. 44 kg's because the remote console and doorbell switch is made optional. (ECR#161201)

Enclosure plastic material changed to Bay Blend FR 3010 PC ABS (ECR # 131202)

7.6.1 CONCLUSION:

Though the Results of impact assessment for individual changes found to be not affecting the safety and effectiveness of device and no modification in the intended use of the

device, we have decided to go for a Special 510 (K) submission to have both the models and update the submission to include all the changes carried out

7.7. INDICATIONS FOR USE

INTRASKAN DC PLUS is High Frequency extra oral X Ray source to be used for Intra-Oral X-Ray in Dental radiography for diagnostic purpose.

The indications for use of subject device and that of predicate device are identical.

7.8. SAFETY, EMC AND PERFORMANCE DATA

Safety and effectiveness is demonstrated by:

Electrical, mechanical, environmental safety and performance testing according to standard UL/IEC 60601-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and, IEC 60601-2-65 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2. All test results were satisfactory. Refer EMC Test Summary & Safety Test Report Summary in section "Electromagnetic Compatibility and Electrical Safety" of this submission document.

Performance testing performed according to FDA 21 CFR 1020.30, 21CFR1020.31 standards, Design Requirement specification, verification & validation plans. All test results were satisfactory. Refer summary of performance in "Performance Testing-Bench" of this submission document.

Same indications for use as predictor.

All the above details combine to demonstrate that the INTRASKAN DC PLUS is safe and effective when the device is used as labeled.

7.9. THE TECHNOLOGICAL CHARACTERISTICS

INTRASKAN DC PLUS has the similar operation and technological characteristics as the predicate devices.

7.10. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(0(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.