K103579

MAR 18 2011

510(K) SUMMARY

As required by CFR section 807.92(c)

5.1 Sponsor

Date:	December 13, 2010
Applicant:	Skanray Technologies Private Limited, Plot # 15-17, Hebbal Industrial Area Mysore-570016, India
Contact Person:	Parasuramappa Belur
Telephone:	+91-821-2415559
Fax:	+91-821-2403344

5.2 Establishment Registration Number

The firm will be registered and listed prior to distribution of medical device.

5.3 Device Name

Trade Name	INTRA SKAN DC
Common Name	High Frequency Intra Oral X-Ray System
Classification Name	76 EHD - Unit, X-Ray, Extra oral with Timer

5.4 Predicate Device

Progeny PREVA	K043092
Dentsply Gx-770:	K935046.
Gendex 765DC:	K992610.

5.5 Product Description

INTRA SKAN DC is a high frequency Intra-oral X-Ray System with an extraoral X-Ray source for dental diagnostic radiography. 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.

INTRA SKAN DC 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

Optional Components:

Long Cone 11.8in (300mm)

9.84 Ft (3m) coiled cord with exposure switch

The Power supply is regulated to provide a selectable 50 to 70 kVp in step of 1kV at a selectable tube current of 4, 6, 7, or 8 mA. The range of exposure times is 0.04 to 4.00 seconds with 1:15 duty. Predefined exposure parameters kV, mA & times may be stored in, selected & operated via the operator control panel.

5.6 Indications for Use

The INTRA SKAN DC Intraoral Dental X-Ray System is to be used as an extraoral source of X-Rays in Dental radiography.

5.7 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 60601-2-32 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 according to FDA 21 CFR 1020.30, 21CFR1020.31 standards, Design Requirement specification & verification and validation plans was performed. All test results were satisfactory. Refer summary of performance in section 18 "Performance Testing-Bench" of this submission document.
- Same indications for use as predicate devices.

All of the above steps combine to demonstrate that the INTRA SKAN DC is safe and effective when the device is used as labelled.

END OF DOCUMENT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Skanray Technologies
% Mr. Morten Christensen
Reviewer/Staff Engineer
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

Re: K103579

MAR 18 2011

Trade/Device Name: INTRA SKAN DC
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source s-ray system
Regulatory Class: II
Product Code: EHD
Dated: March 2, 2010
Received: March 4, 2010

Dear Mr. Christensen:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: INTRA SKAN DC

Indications For Use:

The INTRA SKAN DC Intraoral Dental X-Ray System is to be used as an extraoral source of X-Rays in Dental radiography.

Prescription Use __√____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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