K063456

5. 510(k) Summary

5.1 Submitter:

Topex, Inc.
10 Precision Road
Danbury, CT 06810

Contact Person: Anthony Pellegrino
Telephone: 203-748-5918

JAN - 9 2007

Date Prepared: November 3, 2006

5.2 Device Identification

Proprietary Name: Topex SRT100 Superficial Radiation Therapy System
Common/Usual Name: Superficial Radiation Therapy
Classification Name: X-ray Radiation Therapy Systems and Accessories
Product Code: JAD
CFR Classification: 892.5900

5.3 Predicate Devices

Pantak Superficial X-ray Therapy System (K971074)
Gulmay D3100/Xstrahl 100 (K962613)
Philips RT100 (pre-1976 Amendments device)

5.4 Indications for Use

The SRT100 is a low energy x-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin. Typical applications include basal cell carcinoma, squamous cell carcinoma, metatypic carcinoma, cutaneous appendage carcinoma and Kaposi's sarcoma.

5.5 Device Description

The Topex, Inc. SRT100 is a complete, stand-alone, x-ray radiation therapy system. It consists of two major separate components:

Control Console: Specifically designed module housing the switches and indicators used by the operator to set up and execute x-ray exposures. The controls adjust the machine functions and and settings only, there is no treatment planning capability. The Control Console is connected via cable to the Base Unit.

Base Unit: a cabinet containing the high voltage generator, power supply components, cooling system, and an arm/positioning mechanism on which the x-ray tube housing assembly is mounted. A series of Applicators is included, which are affixed to the x-ray port on the x-ray tube housing assembly to limit the x-ray beam and provide fixed Source-to-Skin Distance (SSD). The X-ray Tube Housing Assembly contains a motorized filter mechanism which move the appropriate beam filter into the beam path depending on the kV setting selected by the operator.

5.6 Principles of Operation

The SRT-100 produces and emits filtered, low energy (70 and 100 kV) x-radiation which is electrically generated using a conventional ceramic x-ray tube. Provision is made to limit the x-radiation to a specified treatment field, and to control the radiation dose to the patient through selection and monitoring of energy, emission level and duration of emission. To mitigate effects of ionizing radiation on healthy cells, and to accumulate more damage in the neoplastic cells, the total dose is fractionated, which means distributing the total dose over a period of time. Typically, 8 to 12 fractions at a rate of 1 to 5 per week are used to deliver a total dose of 40-60 Gy, although larger PMENs may require up to 40 fractions over an 8 week period for a total dose of 80 Gy.[1] (Panizzon, R and Cooper, J. (Eds.) Radiation Treatment and Radiation Reactions in Dermatology, Springer Verlag, 2004, p75)

5.7 Summary of Performance Testing

Performance testing consists of bench testing that demonstrates that the output of the Topex SRT100 provides the same clinical capabilities as the predicate devices. The system successfully passed all tests required by *IEC 60601-1, Part 2-8, Edition 1.1, 1999 – Particular Requirements for the Safety of Therapeutic X-ray Equipment Operating in the Range 10 kV to 1 MV* and also tests developed internally for system characterization.

5.8 Safety Testing

The Topex SRT-100 has been designed and constructed to meet the following electrical and mechanical safety standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- UL 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA-C22.2 NO. 601.1-M90 (R2005): Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-4: **Medical Electrical Equipment--Part 1: General Requirements for Safety-4. Collateral Standard: Programmable Electrical Medical Systems**
- IEC 60601-2-32: MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ASSOCIATED EQUIPMENT OF X-RAY EQUIPMENT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Anthony Pellegrino
CEO
Topex, Inc.
10 Precision Road
DANBURY CT 06810

JAN - 9 2007

Re: K063456
Trade/Device Name: Topex SRT-100 Superficial Radiation Therapy System
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: November 3, 2006
Received: November 21, 2006

Dear Mr. Pellegrino:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063456

Device Name: Topex SRT100Superficial Radiation Therapy System

Indications For Use:

The SRT-100 is a low energy x-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin. Typical applications include basal cell carcinoma, squamous cell carcinoma, Metatypic carcinoma, cutaneous appendage carcinoma and Kaposi's Sarcoma.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063456