SEP 29 1998

510(k) Summary of Safety and Effectiveness
for
Radionics Software Applications, Inc. K981055
XKnife-4

1. SUBMITTER

Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, MA 01803 USA

Contact Person: Lisa Misterka Benati
Senior Regulatory Engineer

2. NAME OF DEVICE

Device Proprietary Name: XKnife-4
Device Common Name: Radiation Treatment Planning System

3. DEVICE CLASSIFICATION

Class II: 21 CFR 892.5900 X-ray Radiation Therapy System

4. DEVICE INTENDED USE

XKnife-4 is intended for use in stereotactic, collimated beam, computer planned, LINAC (linear accelerator) based radiosurgery and radiotherapy treatment.

5. PREDICATE DEVICES

- Radionics Software Applications, Inc. - XKnife-3 System
- Radionics Software Applications, Inc. - XPlan-1 System

6. GENERAL SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use. It includes indications for use, cautions, warnings and user quality assurance procedures. The training and

installation sessions provide assurance that the user understands all aspects of the XKnife-4 System: mechanical, computer and software, plus its intended functionality. This information promotes safe and effective use of the device.

7. COMPARISON OF TECHNICAL CHARACTERISTICS

The XKnife-4 system has similar technical characteristics as the commercially available XKnife-3 system. Both systems consist of treatment planning software, stereotactic hardware and a protocol of extensive verification and QA procedures to ensure proper transfer of the treatment parameters to the clinical delivery system. The XKnife-4 system also has similar technical characteristics as the commercially available XPlan-1 system. Both systems support the use of the LINAC jaws, in addition to a circular collimator, to further shape the radiation beam.

8. NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The design of the XKnife-4 system, including the use of the LINAC jaws, has been thoroughly validated at the unit and system level. Nonclinical tests were conducted to demonstrate that the XKnife-4 software meets all product requirements. This testing also demonstrates that the performance is substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1998

Lisa Misterka Benati
Senior Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, MA 01803

Re: K981055
XKnife-4 Stereoactic RTP System
Dated: July 13, 1998
Received: July 14, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Benati:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981055

Device Name: XKnife-4 Stereotactic Radiosurgery and Radiotherapy Treatment Planning System

Indications For Use:

XKnife-4 is intended for use in stereotactic, collimated beam, computer planned, LINAC (linear accelerator) based radiosurgery and radiotherapy treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981055

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)