NOV 1 8 1999

K990475

KPS & ASSOCIATES, Inc.
Computer Simulation Consultants
(Medical Unit)

Section V - 510(k) Summary
{21 CFR §807.87 (h)/807.92 (a)-(b)}

1.	§807.92(a)(1)	**Submitter's Name:**	KPS & ASSOCIATES, Inc.
		Address:	851 E. Northcrest Drive Salt Lake City, Utah 84103
		Phone: **Fax:** **E-mail:**	(801) 359-4631 (801) 596-8048 kps@aros.net
		Contact Person:	Dr. Krishna P. Sinha
		Date of Summary Preparation:	February 12, 1999
2.	§807.92(a)(2)	**Trade/Proprietary Name:**	*TnPIS*©(Transperineal Prostate Implant Simulator)
		Common/Usual Name:	Treatment Planning and Verification Software for Brachytherapy of Prostate Cancer
		Classification Name:	System, Planning, Radiation Therapy Treatment
		Device Class/Panel:	Class II/Radiology
		Product Code:	MUJ

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Krishna P. Sinha, Ph.D.
President
KPS & Associates, Inc.
Computer Simulation Consultants
(Medical Unit)
851 E. Northcrest Dr.
Salt Lake City, Utah 84103

Re: K990475
TRSPIS-Transperineal Prostate Implant Simulator
Dated: August 19, 1999
Received: August 20, 1999
Regulatory class: II
21 CFR 892.5730/Procode: 90 MUJ

Dear Dr. Sinha:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting 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): K990475

DEVICE NAME: TraPIS

INDICATIONS FOR USE:

TraPIS (Transperineal Prostate Implant Simulator) is a software (computer program) designed for planning and post-implant verification of brachytherapy for carcinoma of the prostate gland. The isotope library includes Palladium (103Pd), Iodine (125I) and Iridium (192Ir) seeds. TraPIS is intended for clinical as well as research and academic use.

In summary, the software is designed to provide a three-dimensional radiation dose distribution in the form of isolines (contours of equal dose) or point-dose-values for a specified seed pattern. An ultrasound-guided prostate boundary dictates the seed locations. A treatment plan consisting of seed strength and distribution can be developed such that the specified radiation dose distribution is achieved within the prostate boundary. Post-implant verification involves relocating the seeds to their actual locations revealed through CT scans and/or radiographs and recalculating the dose distribution.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use__
(Per 21 CFR 801.109) (Optional Format 1-2

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990475