DRAX IMAGE

VIA COURIER

July 17, 2001

Dr. John Jankovich
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD
20852 USA

Subject: **SEALED SOURCE EVALUATION AND REGISTRATION OF BRACHYSEED™ PD-103**

Submission of 510(k)

Dear Dr. Jankovich,

Further to our telephone conversation, we are pleased to provide you with a copy of the 510(k) approval letter issued by the Food and Drug Administration for our **BRACHYSEED™ PD-103** on June 25th, 2001.

Should you require further information concerning this application, please do not hesitate to contact me at (514) 630-7056 or Dr. Richard Flanagan at (514) 630-7039, fax (514) 694-9295.

Sincerely yours,

Carolyne Desrosiers-Clarke
Regulatory Affairs

Encl.

DRAXIMAGE Inc. • 16751 Autoroute TransCanada Highway • Kirkland • Québec • Canada H9H 4J4
• Tél. 888-633-5343 • 514-630-7043 • Fax. 514-694-9295 • Web Site www.draximage.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2001

Mr. Richard J. Flanagan
Executive Vice-President
DRAXIMAGE Inc.
16751 Autoroute TransCanada Highway
KIRKLAND QUEBEC
CANADA H9H 4J4

Re: K011119
BrachySeed Pd-103
Dated: April 6, 2001
Received: April 12, 2001
Regulatory Class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Mr. Flanagan:

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) 594-4639. 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" (21CFR 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,

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 (s)

STATEMENT OF INDICATIONS FOR USE

Applicant: DRAXIMAGE Inc.

510(k) Number (if known): K011119

Device Name: BrachySeed™Pd-103

Indications for Use:

BrachySeed™Pd-103 implants with air kerma strengths up to 3.81U (approx. 3 mCi) are indicated for permanent interstitial implantation in the treatment of selected localized tumors such as tumors of the head, neck, lung, pancreas, breast, uterus and prostate. They can be used either as primary treatment or for residual disease after excision of the primary tumor or for recurring tumors. They may also be used at completion of external beam radiation. BrachySeedPd-103 implants are intended for single use only.

BrachySeedPd-103 implants with strengths greater than 3.81U (approx. 3 mCi) are indicated for temporary implantation or surface application to treat localized tumors.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011119

Perscription Use ✓ (Per 21 CFR 801.1091)

OR

Over-The-Counter Use _____