K 053595

4. 510(k) Summary of Safety and Effectiveness

Device Name:	CuRay™ Custom Seed Array
Device Model Number:	**CSA-xx**
Classification Name:	Radionuclide Brachytherapy Source (KXK), 21 CFR, 892.5730
Device Classification:	Class II
Predicate devices:	TheraLoad (K043596) SeedLink (K023073) Readi-Strand (K023179) RAPID-Strand (K030594) Nag Brachyflex Catheters (Cook, Inc.)
Manufacturer:	BioLucent, Inc. 6 Journey, Suite 325 Aliso Viejo, CA 92656
Establishment Registration Number:	2032338
Official Contact:	Sheryl Higgins BioLucent, Inc. 6 Journey, Suite 325 Aliso Viejo, CA 92656 Phone: (949) 349-1380 (x101)

Intended Use:
CuRay Custom Seed Array is a sterile, custom loaded, brachytherapy seed assembly intended to treat localized tumors such as tumors of the head, neck, lung, pancreas, breast, uterus, cervix and prostate. It can be used either as primary treatment or for residual disease after excision of the primary tumor or for recurring tumors. It may also be used concurrent with or at the completion of other treatment modalities such as external beam radiation therapy or chemotherapy.

Device Description:
The CuRay Custom Seed Array is an integral assembly containing radionuclide source seeds, spacers, and markers which are custom loaded according to a prescribed treatment plan. The CuRay Custom Seed Array is provided sterile and is a single use device.

Technological Characteristics Summary
The CuRay Custom Seed Array is equivalent to the predicate devices, with the same principles of operation and overall technological characteristics.

Performance Data Summary
Performance testing was conducted on the CuRay Custom Seed Array to demonstrate the integrity, suitability and substantial equivalence of the device.

Conclusion:
Upon reviewing the safety and efficacy information provided in this submission and , comparing intended use, principle of operation and overall technological characteristics, the CuRay Custom Seed Array is determined to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2006

Ms. Sheryl W. Higgins
Director of Engineering
BioLucent, Inc.
6 Journey, Suite 325
ALISO VIEJO CA 92656

Re: K053595
Trade/Device Name: CuRay Custom Seed Array
Regulation Number: 21 CFR §892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: December 21, 2005
Received: December 23, 2005

Dear Ms. Higgins:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 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

3. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053595

Device Name:

CuRay Custom Seed array

Indications for Use:

CuRay Custom Seed Array is a sterile, custom loaded, brachytherapy seed assembly intended to treat localized tumors such as tumors of the head, neck, lung, pancreas, breast, uterus, cervix and prostate. It can be used either as primary treatment or for residual disease after excision of the primary tumor or for recurring tumors. It may also be used concurrent with or at the completion of other treatment modalities such as external beam radiation therapy or chemotherapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

/Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053595