4. 510(k) Summary of Safety and Effectiveness

K062141

Device Name:	MammoPad Radiolucent Cushion
Classification Name:	Accessory to X-Ray Mammographic System (IZH), 21 CFR, 892.1710 Accessory to Scintillation (Gamma) Camera (IYX) 21 CFR, 892.1100
Device Classification:	Class II (IZH) Class I (IYX)
Predicate devices:	MammoPad® (K003795) Scintimammography Pad Set, PineStar Technology Scintimammography Pad, Cone Instruments
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:
MammoPad is intended to provide padding for patient comfort and aid in positioning during radiologic visualization of the breast using x-ray or scintillation technology.

Device Description:
MammoPad is a radiolucent foam cushion used during radiologic visualization of the breast. MammoPad is non-sterile and is a single use device.

K062141

Technological Characteristics/Performance Data Summary
MammoPad is equivalent to the predicate devices, with the same principles of operation and overall technological characteristics.

Conclusion:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, MammoPad is determined to be substantially equivalent to an existing legally marketed device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 13 2006

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

Re: K062141
Trade/Device Name: MammoPad Radiolucent Cushion
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IYX and IZH
Dated: July 26, 2006
Received: July 27, 2006

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.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

3. **Indications for Use Statement**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K062141

Device Name:

MammoPad Radiolucent Cushion

Indications for Use:

Provide padding for patient comfort and aid in positioning during radiologic visualization of the breast using x-ray or scintillation technology.

(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 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062141