K031574
Page 1 of 3

AUG - 4 2003

Exhibit # 1

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

   S&S Technology
   a Division of
   S&S X-Ray Products, Inc.
   10625 Telge Road
   Houston, TX 77095

   Contact Dr. Norman Shoenfeld

   Date Summary Prepared:

   May 16, 2003

2. **Name of the Device:**

   The Squeeze-Ease™ Mammography Cushion

3. **Predicate Device Information:**

   K#003795, Biolucent Mammography Cushion, Biolucent, Inc., Aliso Viejo, CA

4. **Device Description:**

   The Squeeze-Ease™ Mammography Cushion is placed on both compression surfaces of the mammography machine. The pads can be cleaned with mild soap and water and disinfected with a hospital disinfecting solution, either Cavicide™ or T-Spray™ II.

   The Squeeze-Ease™ Mammography Cushion is mounted on the specified mammography machine, for which it was designed, using the included Velcro strips. First, the cushion is placed so that it is centered on the imaging area, and

slightly overlaps the edge, which is directed toward the front of the machine, where the patient's chest wall will contact the machine. After placement on the machine, the cushion needs to be secured to the machine using the Velcro strips.

The pads are cleaned/disinfected prior to use with the next patient. Any questions of cushion-induced artifact (or artifact caused by foreign body trapped between the cushions and the mammography machine) should be ruled out immediately by taking a test image using the cushions alone. The materials used in the Squeeze-Ease™ Mammography Cushions have been selected to be radiolucent and do not interfere with the mammography image. The cushion pad has been designed to be radiolucent at the energy levels used in mammography exams.

5. **Intended Use:**

The Squeeze-Ease™ Mammography Cushion provides padding for patient comfort during X-ray visualization of the breast.

6. **Comparison to Predicate Devices:**

The "Indications for Use" are identical to the predicate. The differences include: the predicate is single-use, disposable, while the subject device is reusable. The subject device material consists of polyurethane patient-contact, with the core (non-patient contact) consisting of cross-linked polyethylene. The predicate device consists of an open cell foam pad.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

A study showing radiolucency of The Squeeze-Ease™ Mammography Cushion was conducted which demonstrated no difference in the image with the subject device in place.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The Squeeze-Ease™ Mammography Cushion has the same intended use and similar characteristics as the predicate device. Moreover, documentation supplied in this submission demonstrates that any differences in their characteristics do not raise any new questions of safety to effectiveness. Thus, the Squeeze-Ease™ Mammography Cushion is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2003

S&S X-Ray Products, Inc.
% Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K031574
Trade/Device Name: Squeeze-Ease Mammography Cushion
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: July 11, 2003
Received: July 14, 2003

Dear Ms. Goldstein-Falk:

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 (PMA), it may be subject to 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 the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/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

Exhibit B



510(k) Number (if known): K031574

Device Name: Squeeze-Ease™ Mammography Cushion

Indications For Use:

The Squeeze-Ease™ Mammography Cushion provides padding for patient comfort during x-ray visualization of the breast.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031574