K973450
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NOV 14 1997

510(k) SUMMARY
Sensor Pad®
September 9, 1997

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k) premarket notification was in accordance with 21CFR 807.87 and the SMDA.

1. **Submitter of 510(k)**

Company Name:	Inventive Products, Inc.
Address:	1450 East North Street Decatur, Illinois 62521
Contact Person:	Grant Wright, President
Telephone:	(217) 423-6911
Fax:	(217)423-7282

2. **Name of Device**:

Trade/Proprietary Name:

Sensor Pad®

Common/Usual Name:

Aid for breast self-examination

Classification Name

21 CFR 892.1710 "Mammographic x-ray system (accessory)"
Class I

3. **Legally Market Predicate Devices**

The Sensor Pad® cleared under 510(k) K955249

K973450

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4. Device Description

The Sensor Pad® is a thin polyether polyurethane bladder, 9.5 inches in diameter,containing a small quantity of a lubricating fluid. The very thin nature of the polyether polyurethane allows the pad to conform to the shape of the tissues underlying it. The very low coefficient of friction property of the silicone fluid in combination with the very thin and flexible bladder, results in an easy sliding relationship between the upper and lower surfaces of the bladder. Therefore when properly used between the finger and the soft tissues of the patient, a reduction of friction is observed.

Performance testing of the Sensor Pad's® use on tactile examination was extensively investigated. These studies were provided and described in detail. The reported data included descriptions of the protocols, findings, and conclusions. Physical tests demonstrated the Sensor Pad's® ability to reduce friction, as measured as the coefficient of friction. Biocompatibility data pertinent to the materials used in the manufacture of the Sensor Pad® were also provided. Six clinical studies were reported. These studies included investigations of the tactile detection of lumps using the Sensor Pad® as compared to using a lubricant and/or unaided detection, as well as the clinical performance of the Sensor Pad® during breast self-examination. Additional testing was also conducted to answer additional questions relating to OTC clearance. Results were provided and demonstrate that a change from "Prescription Use Only" to "OTC Use" does not in any way alter the intended use or the safety or effectiveness of this device.

5. Intended Use

The Sensor Pad® is indicated as an aid for performing breast self-examination.

6. Substantial Equivalence

The Sensor Pad® is physically identical and has the same indication for use as that previously cleared under K955249. This application is to change from "Prescription Use Only" to OTC. The Sensor Pad® previously cleared thus serves as the legally marketed predicate device. Valid scientific evidence, as discussed above, was provided to demonstrate the substantial equivalence determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 1997

Mr. Grant A. Wright
President
Inventive Products, Inc.
1450 East North Street
Decatur, Illinois 62521

Re: K973450
Sensor Pad® - OTC
Dated: September 9, 1997
Received: September 11, 1997
Regulatory class: II
21 CFR §892.1710/Product code: 90 IXH

Dear Mr. Wright:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
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): K973450

Device Name: Sensor Pad

Indications For Use:

"The Sensor Pad is indicated as an aid for performing breast self-examination".

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973450

Prescription Use____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1998

Mr. Grant Wright
President
Inventive Products, Inc.
1450 East North Street
Decatur, Illinois, 62521

Re: K973450
Sensor Pad® - OTC
Dated: September 9, 1997
Received: September 11, 1997
Regulatory Class: II
21 CFR 892.1560
Product Code: 90 IYO

Dear Mr. Wright:

This letter corrects our substantially equivalent letter of November 14, 1997, regarding the CFR classification number from 892.1710 to 892.1560 and product code for 90 IXH to 90 IYO. We apologize for the error and any inconvenience it may have caused.

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.

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This letter will allow you to continue 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.

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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): K973450

Device Name: Sensor Pad

Indications For Use:

"The Sensor Pad is indicated as an aid for performing breast self-examination".

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973450

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)