K072541

SENORX

SEP 25 2007

## 5. 510(K) SUMMARY

| | |
|---|---|
| **Prepared date** | August 21, 2007 |
| **510(k) owner** | **SenoRx, Inc.**<br>11 Columbia<br>Aliso Viejo, CA 92656<br>P. 949.362.4800 F. 949.362.3200 |
| **Contact person** | Eben Gordon |
| **Device name** | SenoSonix Ultrasound Breast Biopsy System |
| **Common name** | Biopsy device<br>Ultrasound Imaging System |
| **Classification name** | Gastroenterology-urology biopsy instrument 876.1075 KNW<br>*Diagnostic Ultrasound Module*<br>Ultrasonic Pulsed Doppler Imaging System 892.1550 TYN<br>Ultrasonic Pulsed Echo Imaging System 892.1560 IYO<br>Diagnostic Ultrasound Transducer 892.1570 ITX |
| **Review category** | Tier II |
| **Regulatory class** | II |
| **Predicate device** | K023923 SenoCor 360 Circumferential Vacuum-Assisted Biopsy Device<br>K040842 SenoRx Biopsy Device II<br>K061827 Sonix Ultrasound Scanner |
| **Decision date** | 12/11//2002 (K023923)<br>4/30/2004 (K040842)<br>8/4/2006 (K061827) |
| **Device description** | The SenoSonix System is a percutaneous ultrasound-guided, vacuum-assisted biopsy device which is intended for use in providing breast tissue samples for diagnostic sampling of breast abnormalities.<br><br>The SenoSonix System integrates the functions of the existing SenoRx Control Module (K023923) and Vacuum System (K023923) into a single console. An added feature of the SenoSonix System is the integration of Ultrasonix Medical's Sonix Ultrasound Scanner (K061827).<br><br>The SenoSonix System has 2 flat panel displays. One displays the ultrasound image and the other is for user operation and |

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control. The biopsy module will be controlled by the small window on the touch screen when the biopsy tab is selected.

**Indications for use**

The SenoSonix Ultrasound Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The ultrasound module is intended for use in obstetrics/gynecology and general radiology examinations by a qualified physician, to aid in the diagnosis and evaluation of soft tissues, by generating 2 dimensional images, time motion images and biometric studies.

The specific intended uses of the ultrasound system include: abdominal, small parts, peripheral vascular, musculo-skeletal (conventional), musculo-skeletal (superficial), small organ (breast, thyroid, testicle), pediatric and fetal imaging.

**Summary of substantial equivalence**

The indications for use for the SenoSonix System are a sub-set of the predicate devices. The design changes that have occurred to the SenoRx Biopsy System and the Sonix Ultrasound System are limited to those to take advantage of a shared console, keyboard, and display.

The software is only changed to integrate the functionality of the control module, vacuum system, and ultrasound module into a common console.

The SenoSonix System has the following similarities to that of the previously cleared predicate devices:

- Has the same intended use;
- Uses the same operating principle and has not altered the fundamental technology;
- Incorporates the same biopsy and ultrasound probes;
- Incorporates the same patient contacting materials; and
- Has the same manufacturing materials and processes

In summary, the SenoSonix Ultrasound Breast Biopsy System described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2007

SenoRx, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K072541
Trade/Device Name: SenoSonix Ultrasound Breast Biopsy System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 7, 2007
Received: September 10, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket 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.

This determination of substantial equivalence applies to the following transducers intended for use with the SenoSonix Ultrasound Breast Biopsy System, as described in your premarket notification:

Transducer Model Number

C5-2/60 convex 1/5MHz 60mm radius
L14-5/38 linear 5/12MHz 38mm
L14-5W/60 linear 5/12MHz 60mm
L9-4/38 linear 4/9MHz 38mm

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

**SenoSonix Ultrasound Module**

## Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | N | N | N | | N | N | N | N (a) | N (b) |
| Abdominal | | N | N | N | N | N | N | N | N (a) | N (b) |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | N | N | N | N | N | N | N | N (a) | N (b) |
| Small Organ (specify) | | N | N | N | | N | N | N | N (a) | N (b) |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | N | N | N | | N | N | N | N (a) | N (b) |
| Laparoscopic | | | | | | | | | | |
| MSK Conventional | | N | N | N | | N | N | N | N (a) | N (b) |
| MSK Superficial | | N | N | N | | N | N | N | N (a) | N (b) |
| Other (specify) (c) | | | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
Intraoperative: abdominal organs and vascular
(a) B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
(b) Freehand 3D imaging, live 3D imaging, Directional Power Doppler (DPD)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072541

**C5-2/60 convex 1/5MHz 60mm radius transducer**

## Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | P | P (a) | P (b) |
| Abdominal | | P | P | P | | P | P | P | P (a) | P (b) |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | P | P (a) | P (b) |
| Small Organ (specify) | | P | P | P | | P | P | P | P (a) | P (b) |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | P | P | P | P (a) | P (b) |
| Laparoscopic | | | | | | | | | | |
| MSK Conventional | | P | P | P | | P | P | P | P (a) | P (b) |
| MSK Superficial | | P | P | P | | P | P | P | P (a) | P (b) |
| Other (specify) | | | | | | | | | | |

N=new indication; P=previously cleared by FDA (Ultrasonix Medical Corp. in K061827); E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
(a) B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
(b) Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072541

**L14-5/38 linear 5/12MHz 38mm transducer**

## Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | P | P (a) | P (b) |
| Abdominal | | P | P | P | | P | P | P | P (a) | P (b) |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | P | P (a) | P (b) |
| Small Organ (specify) | | P | P | P | | P | P | P | P (a) | P (b) |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | P | P | P | P (a) | P (b) |
| Laparoscopic | | | | | | | | | | |
| MSK Conventional | | P | P | P | | P | P | P | P (a) | P (b) |
| MSK Superficial | | P | P | P | | P | P | P | P (a) | P (b) |
| Other (specify) | | | | | | | | | | |

N=new indication (previously cleared by Ultrasonix Medical Corp. in K061827); P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
(a) B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
(b) Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072544

**L14-5W/60 linear 5/12MHz 60mm transducer**

## Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | P | P (a) | P (b) |
| Abdominal | | P | P | P | | P | P | P | P (a) | P (b) |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | P | P (a) | P (b) |
| Small Organ (specify) | | P | P | P | | P | P | P | P (a) | P (b) |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | P | P | P | P (a) | P (b) |
| Laparoscopic | | | | | | | | | | |
| MSK Conventional | | P | P | P | | P | P | P | P (a) | P (b) |
| MSK Superficial | | P | P | P | | P | P | P | P (a) | P (b) |
| Other (specify) | | | | | | | | | | |

N=new indication (previously cleared by Ultrasonix Medical Corp. in K061827); P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
(a) B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
(b) Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072541

**L9-4/38 linear 4/9MHz 38mm transducer**

## Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | P | P (a) | P (b) |
| Abdominal | | P | P | P | | P | P | P | P (a) | P (b) |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | P | P (a) | P (b) |
| Small Organ (specify) | | P | P | P | | P | P | P | P (a) | P (b) |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | P | P | P | P (a) | P (b) |
| Laparoscopic | | | | | | | | | | |
| MSK Conventional | | P | P | P | | P | P | P | P (a) | P (b) |
| MSK Superficial | | P | P | P | | P | P | P | P (a) | P (b) |
| Other (specify) | | | | | | | | | | |

N=new indication (previously cleared by Ultrasonix Medical Corp. in K061827& K042326); P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
(a) B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
(b) Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071254

# 4. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: _____ SenoSonix Ultrasound Breast Biopsy System 510(k) Submission _____

Indications for Use:

The SenoSonix Ultrasound Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

The ultrasound module is intended for use in obstetrics/gynecology and general radiology examinations by a qualified physician, to aid in the diagnosis and evaluation of soft tissues, by generating 2 dimensional images, time motion images and biometric studies.

The specific intended uses of the ultrasound system include: abdominal, small parts, peripheral vascular, musculo-skeletal (conventional), musculo-skeletal (superficial), small organ (breast, thyroid, testicle), pediatric and fetal imaging.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072544

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