



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Yasuhuru Ishii  
Manager, Ultrasound Product  
Engineering and Technical Support  
Shimazu Medical Systems  
20101 South Vermont Ave.  
Torrence, CA 90502

AUG - 4 1997

Re: K970508  
Echo View SDU-2000 Diagnostic Ultrasound System  
Dated: June 20, 1997  
Received: June 23, 1997  
Regulatory class: II  
21 CFR 892.1550/Procode: 90 IYO

Dear Mr. Yashuhuru:

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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SDU-2000, as described in your premarket notification:

Transducer Model Number

2.5 MHz PA SECTOR

3.5 MHz PA SECTOR

5.0 MHz PA SECTOR

3.5 MHz R40 CA CONVEX

3.5 MHz R76 CA CONVEX

7.5 MHz LA LINEAR ARRAY

5.5 MHz TV CONVEX

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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

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.

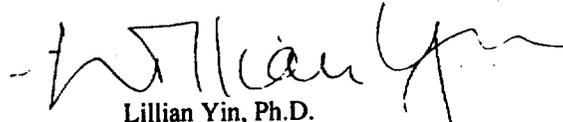
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the 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 at (301) 443-6597 or at its internet address <http://www.fda.gov/cdrh/dsmamain.htm>.

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If you have any questions regarding the content of this letter, please contact **Maureen Butler** at (301) 594-1212.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian Yin". The signature is fluid and cursive, with a long horizontal stroke at the end.

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) : \_\_\_\_\_  
 Device Name : Diagnostic Ultrasound System SDU-2000, PA probe 2.5

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis  
 of the human body as follows:

Mode of Operation

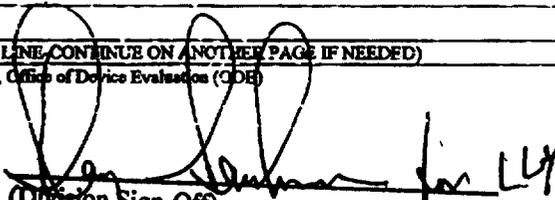
| Clinical Application         | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify)** | Other (Specify) |
|------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|----------------------|-----------------|
| Ophthalmic                   |   |   |   |     |     |               |                           |                        |                      |                 |
| Fetal                        |   |   |   |     |     |               |                           |                        |                      |                 |
| Abdominal                    |   |   |   | X   |     | X             | X                         |                        |                      |                 |
| Intra-operative (Specify)    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative Neurological |   |   |   |     |     |               |                           |                        |                      |                 |
| Pediatric                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Small Organ (Specify) *      |   |   |   |     |     |               |                           |                        |                      |                 |
| Neonatal Cephalic            |   |   |   |     |     |               |                           |                        |                      |                 |
| Adult Cephalic               |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Adult                |   | X | X | X   | X   | X             | X                         | X                      | X                    |                 |
| Cardiac Pediatric            |   | X | X | X   | X   | X             | X                         | X                      | X                    |                 |
| Trans-esophageal             |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-rectal                 |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-vaginal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-luminal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-utethral               |   |   |   |     |     |               |                           |                        |                      |                 |
| Peripheral vessel            |   |   |   |     |     |               |                           |                        |                      |                 |
| Laparoscopic                 |   |   |   |     |     |               |                           |                        |                      |                 |

Other Indications or Modes:

\*\* B/M, B/PWD, Color/PWD, B/PWD/M, Color/M and Color/PWD/M mode

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K970508

d

510(k) Number (if known) : \_\_\_\_\_  
 Device Name : Diagnostic Ultrasound System SDU-2000, PA probe 3.5

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis  
 of the human body as follows: \_\_\_\_\_

Mode of Operation

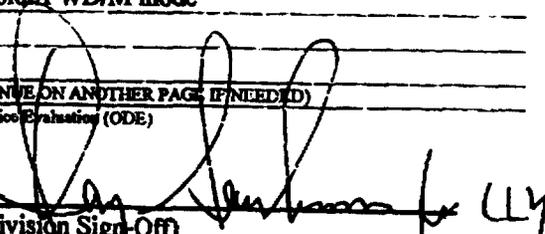
| Clinical Application         | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify)** | Other (Specify) |
|------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|----------------------|-----------------|
| Ophthalmic                   |   |   |   |     |     |               |                           |                        |                      |                 |
| Fetal                        |   |   |   |     |     |               |                           |                        |                      |                 |
| Abdominal                    |   |   |   | X   |     | X             | X                         |                        |                      |                 |
| Intra-operative (Specify)    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative Neurological |   |   |   |     |     |               |                           |                        |                      |                 |
| Pediatric                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Small Organ (Specify) *      |   |   |   |     |     |               |                           |                        |                      |                 |
| Neonatal Cephalic            |   |   |   |     |     |               |                           |                        |                      |                 |
| Adult Cephalic               |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Adult                |   | X | X | X   | X   | X             | X                         | X                      | X                    |                 |
| Cardiac Pediatric            |   | X | X | X   | X   | X             | X                         | X                      | X                    |                 |
| Trans-esophageal             |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-rectal                 |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-vaginal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-luminal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-utethral               |   |   |   |     |     |               |                           |                        |                      |                 |
| Peripheral vessel            |   |   |   |     |     |               |                           |                        |                      |                 |
| Laparoscopic                 |   |   |   |     |     |               |                           |                        |                      |                 |

Other Indications or Modes:

\*\* B/M, B/PWD, Color/PWD, B/PWD/M, Color/M and Color/PWD/M mode

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Concurrent use of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K970508

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510(k) Number (if known) : \_\_\_\_\_  
 Device Name : Diagnostic Ultrasound System SDU-2000, PA probe 5.0

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis  
 of the human body as follows: .....

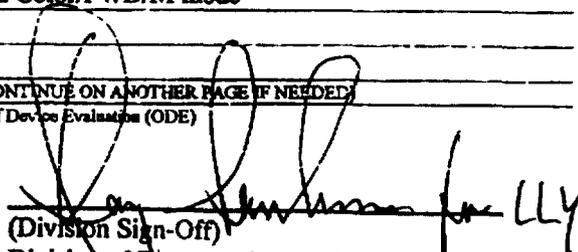
**Mode of Operation**

| Clinical Application         | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify)** | Other (Specify) |
|------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|----------------------|-----------------|
| Ophthalmic                   |   |   |   |     |     |               |                           |                        |                      |                 |
| Fetal                        |   |   |   |     |     |               |                           |                        |                      |                 |
| Abdominal                    |   |   |   | X   |     | X             | X                         |                        |                      |                 |
| Intra-operative (Specify)    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative Neurological |   |   |   |     |     |               |                           |                        |                      |                 |
| Pediatric                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Small Organ (Specify) *      |   |   |   |     |     |               |                           |                        |                      |                 |
| Neonatal Cephalic            |   |   |   |     |     |               |                           |                        |                      |                 |
| Adult Cephalic               |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Adult                |   | X | X | X   | X   | X             | X                         | X                      | X                    |                 |
| Cardiac Pediatric            |   | X | X | X   | X   | X             | X                         | X                      | X                    |                 |
| Trans-esophageal             |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-rectal                 |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-vaginal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-luminal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-utethral               |   |   |   |     |     |               |                           |                        |                      |                 |
| Peripheral vessel            |   |   |   |     |     |               |                           |                        |                      |                 |
| Laparoscopic                 |   |   |   |     |     |               |                           |                        |                      |                 |

Other Indications or Modes:

\*\* B/M, B/PWD, Color/PWD, B/PWD/M, Color/M and Color/PWD/M mode

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number R970508

510(k) Number (if known) : \_\_\_\_\_  
 Device Name : Diagnostic Ultrasound System SDU-2000, CA probe 3.5 R40

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis  
 of the human body as follows: \_\_\_\_\_

**Mode of Operation**

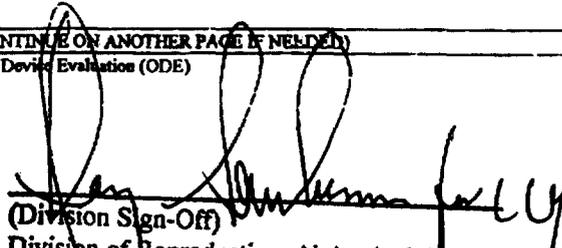
| Clinical Application         | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify)** | Other (Specify) |
|------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|----------------------|-----------------|
| Ophthalmic                   |   |   |   |     |     |               |                           |                        |                      |                 |
| Fetal                        |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Abdominal                    |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Intra-operative (Specify)    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative Neurological |   |   |   |     |     |               |                           |                        |                      |                 |
| Pediatric                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Small Organ (Specify) *      |   |   |   |     |     |               |                           |                        |                      |                 |
| Neonatal Cephalic            |   |   |   |     |     |               |                           |                        |                      |                 |
| Adult Cephalic               |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Adult                |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Pediatric            |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-esophageal             |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-rectal                 |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-vaginal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-luminal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-utethral               |   |   |   |     |     |               |                           |                        |                      |                 |
| Peripheral vessel            |   |   |   |     |     |               |                           |                        |                      |                 |
| Laparoscopic                 |   |   |   |     |     |               |                           |                        |                      |                 |

Other Indications or Modes:

\*\* B/M, B/PWD, Color/PWD, B/PWD/M, Color/M and Color/PWD/M mode

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Pediatric Devices

510(k) Number (if known) : \_\_\_\_\_  
 Device Name : Diagnostic Ultrasound System SDU-2000, CA probe 3.5 R76

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis  
 of the human body as follows: \_\_\_\_\_

**Mode of Operation**

| Clinical Application         | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify)** | Other (Specify) |
|------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|----------------------|-----------------|
| Ophthalmic                   |   |   |   |     |     |               |                           |                        |                      |                 |
| Fetal                        |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Abdominal                    |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Intra-operative (Specify)    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative Neurological |   |   |   |     |     |               |                           |                        |                      |                 |
| Pediatric                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Small Organ (Specify) *      |   |   |   |     |     |               |                           |                        |                      |                 |
| Neonatal Cephalic            |   |   |   |     |     |               |                           |                        |                      |                 |
| Adult Cephalic               |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Adult                |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Pediatric            |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-esophageal             |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-rectal                 |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-vaginal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-luminal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-utethral               |   |   |   |     |     |               |                           |                        |                      |                 |
| Peripheral vessel            |   |   |   |     |     |               |                           |                        |                      |                 |
| Laparoscopic                 |   |   |   |     |     |               |                           |                        |                      |                 |

Other Indications or Modes:

\*\* B/M, B/PWD, Color/PWD, B/PWD/M, Color/M and Color/PWD/M mode

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K970508

510(k) Number (if known) : \_\_\_\_\_

Device Name : Diagnostic Ultrasound System SDU-2000, LA probe 7.5 PV

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis  
of the human body as follows:

**Mode of Operation**

| Clinical Application         | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify)** | Other (Specify) |
|------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|----------------------|-----------------|
| Ophthalmic                   |   |   |   |     |     |               |                           |                        |                      |                 |
| Fetal                        |   |   |   |     |     |               |                           |                        |                      |                 |
| Abdominal                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative (Specify)    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative Neurological |   |   |   |     |     |               |                           |                        |                      |                 |
| Pediatric                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Small Organ (Specify) *      |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Neonatal Cephalic            |   |   |   |     |     |               |                           |                        |                      |                 |
| Adult Cephalic               |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Adult                |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Pediatric            |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-esophageal             |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-rectal                 |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-vaginal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-luminal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-utethral               |   |   |   |     |     |               |                           |                        |                      |                 |
| Peripheral vessel            |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Laparoscopic                 |   |   |   |     |     |               |                           |                        |                      |                 |

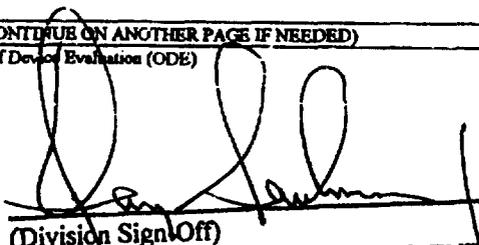
Other Indications or Modes:

\* Thyroid, Testicles, Breast

\*\* B/M, B/PWD, Color/PWD, B/PWD/M, Color/M and Color/PWD/M mode

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K970508

Prescription Use (Per 21 CFR 801.109)

510(k) Number (if known) : \_\_\_\_\_  
 Device Name : Diagnostic Ultrasound System SDU-2000, TV probe 5.5 11R

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis  
 of the human body as follows:

**Mode of Operation**

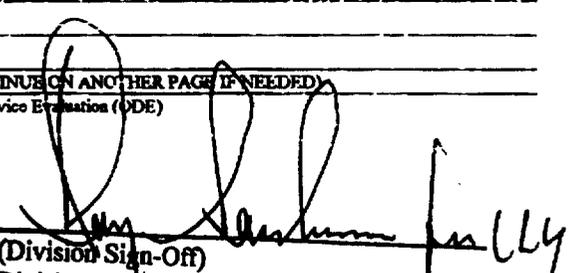
| Clinical Application         | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify)** | Other (Specify) |
|------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|----------------------|-----------------|
| Ophthalmic                   |   |   |   |     |     |               |                           |                        |                      |                 |
| Fetal                        |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Abdominal                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative (Specify)    |   |   |   |     |     |               |                           |                        |                      |                 |
| Intra-operative Neurological |   |   |   |     |     |               |                           |                        |                      |                 |
| Pediatric                    |   |   |   |     |     |               |                           |                        |                      |                 |
| Small Organ (Specify) *      |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Neonatal Cephalic            |   |   |   |     |     |               |                           |                        |                      |                 |
| Adult Cephalic               |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Adult                |   |   |   |     |     |               |                           |                        |                      |                 |
| Cardiac Pediatric            |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-esophageal             |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-rectal                 |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Trans-vaginal                |   | X | X | X   |     | X             | X                         | X                      | X                    |                 |
| Intra-luminal                |   |   |   |     |     |               |                           |                        |                      |                 |
| Trans-utethral               |   |   |   |     |     |               |                           |                        |                      |                 |
| Peripheral vessel            |   |   |   |     |     |               |                           |                        |                      |                 |
| Laparoscopic                 |   |   |   |     |     |               |                           |                        |                      |                 |

Other Indications or Modes:

\*\* B/M, B/PWD, Color/PWD, B/PWD/M, Color/M and Color/PWD/M mode

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Concurrence of CDRII, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K970508