

## Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

K061437

JUN 14 2006

### 1. Submitter Information

- a. Submitter: Kontron Medical SAS  
52, rue Pierre Curie  
78373 Plaisir, Yveline  
France
- b. Contact Person: Mr. Larry Walker  
Fukuda Denshi USA INC.  
17725 N.E. 65<sup>th</sup> Street Bldg. C  
Redmond, WA 98052-4911  
Phone: 800-365-6668  
Fax: 425-869-2018
- c. Date Prepared: 07 February 2006

### 2. Name of device

- a. Trade name: Sigma 5000 series, Imagic
- b. Common name: Medical Diagnostic Ultrasound Imaging System and transducers
- c. Classification name: Ultrasonic Pulsed Doppler Imaging System 21 CFR 892.1550 90-IYN  
Ultrasonic Pulsed Echo Imaging System 21 CFR 892.1560 90-IYO  
Diagnostic Ultrasonic Transducer 21 CFR 892.1570 90-ITX

### 3. Equivalent Legally-Marketed Devices:

Kontron Medical Sigma 110/330, K002239

The technological characteristics of the predicate device are the same as those of the new device.

### 4. Description

This submission will add a Adult Cephalic (Adult Transcranial) indication for use to the Sigma 5000 series, Imagic, which was already cleared with the following diagnostic ultrasound investigations: Imaging (B-mode), Time motion (M-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler), Color Flow Mapping (CFM) and Color Time motion (CM mode), see K050099 and K053084.

5. Intended use

K061437

Diagnostic ultrasound investigations: Imaging (B-mode), Time motion (M-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler), Color Flow Mapping (CFM) and Color Time motion (CM mode).

6. Performance Data

- a. Non-clinical tests: The device has been evaluated for acoustic output and thermal, and has been found conform with applicable medical device safety standards. Cleared patient contact materials, electrical and mechanical safety are unchanged.
- b. Clinical tests: Since the Sigma 5000 series Imagic uses the same technology and principles as existing devices, clinical tests are not required.
- c. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Kontron Medical that the Sigma 5000 series Imagic is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 14 2006

Kontron Medical S.A.S.  
% Mr Robert Mosenkis  
President  
CITECH  
5200 Butler Pike  
PLYMOUTH MEETING PA 19462-1298

Re: K061437

Trade Name: Sigma 5000 series, Imagic  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: May 23, 2006  
Received: May 24, 2006

Dear Mr. Mosenkis:

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 Sigma 5000 series, Imagic, as described in your premarket notification:



Transducer Model Number

2-4 PA  
2-5 CA  
3-8 PA  
3-8 TEM  
4-9EC  
5-12 LA  
5-12 L50  
2 MHz Pen  
8 MHz Pen

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 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 September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." 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:

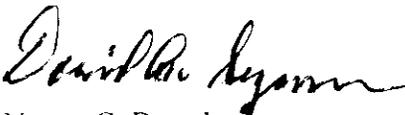
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

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), 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 Ralph Shuping, Sc.D at (301) 594-1212.

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)

K061437

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

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

| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Abdominal                     |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neurological   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Small organs (specify)        |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   | N | N | N    | N    | N             | N                 |                        | N                  |                 |
| Cardiac                       |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Transesophageal               |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Transrectal                   |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Transvaginal                  |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Musculo-skeletal Superficial  |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments:

- Small organs: Thyroid, Breast, Testicle
- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Agoston*

(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal,  
and Radiological Devices

Device Number

K061437

*K061437*

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

Transducer: 2-4 PA

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

| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   |   |   |      |      |               |                   |                        |                    |                 |
| Abdominal                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neuro-logical  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Small organs (specify)        |                   |   |   |      |      |               |                   |                        |                    |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   | N | N | N    | N    | N             | N                 |                        | N                  |                 |
| Cardiac                       |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Transesophageal               |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   | N | N | N    | N    | N             | N                 |                        | N                  |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Superficial  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments:

- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David H. Johnson*

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

Device Number

*K061437*

K061437

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

Transducer: 2-5 CA

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

| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Abdominal                     |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neurological   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Small organs (specify)        |                   |   |   |      |      |               |                   |                        |                    |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   |   |   |      |      |               |                   |                        |                    |                 |
| Cardiac                       |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transesophageal               |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   | N | N | N    |      | N             | N                 |                        | N                  |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Superficial  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments:

- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David R. Johnson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number

K061437

K061437

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

Transducer: 3-8 PA

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

| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   |   |   |      |      |               |                   |                        |                    |                 |
| Abdominal                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neuro-logical  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Small organs (specify)        |                   |   |   |      |      |               |                   |                        |                    |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   |   |   |      |      |               |                   |                        |                    |                 |
| Cardiac                       |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Transesophageal               |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   |   |   |      |      |               |                   |                        |                    |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Superficial  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments:

- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David B. Seymour*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 Number: K061437

*KOL 1437*

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

Transducer: 3-8 TEM

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

| Clinical Application          | Mode of Operation |   |   |         |         |                  |                      |                              |                       |                    |
|-------------------------------|-------------------|---|---|---------|---------|------------------|----------------------|------------------------------|-----------------------|--------------------|
|                               | A                 | B | M | PW<br>D | CW<br>D | Color<br>Doppler | Amplitude<br>Doppler | Color<br>Velocity<br>Imaging | Combined<br>(specify) | Other<br>(specify) |
| Ophthalmic                    |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Fetal                         |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Abdominal                     |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Intraoperative (specify)      |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Intraoperative Neuro-logical  |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Pediatric                     |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Small organs (specify)        |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Neonatal Cephalic             |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Adult Cephalic                |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Cardiac                       |                   | P | P | P       | P       | P                | P                    |                              | P                     |                    |
| Transesophageal               |                   | P | P | P       | P       | P                | P                    |                              | P                     |                    |
| Transrectal                   |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Transvaginal                  |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Transurethral                 |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Intravascular                 |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Peripheral Vascular           |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Laparoscopic                  |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Musculo-skeletal Conventional |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Musculo-skeletal Superficial  |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Other (specify)               |                   |   |   |         |         |                  |                      |                              |                       |                    |

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

Additional Comments:

- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David H. Seymour*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 (Track) Number *2061437*

K061437

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic Transducer: 4-9EC

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

| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Abdominal                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neuro-logical  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Small organs (specify)        |                   |   |   |      |      |               |                   |                        |                    |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   |   |   |      |      |               |                   |                        |                    |                 |
| Cardiac                       |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transesophageal               |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transrectal                   |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Transvaginal                  |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   |   |   |      |      |               |                   |                        |                    |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Superficial  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments:

- Small organs: Thyroid, Breast, Testicle
- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

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

Case Number

K061437

*K061437*

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

Transducer: 5-12 LA

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

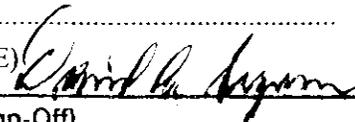
| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   |   |   |      |      |               |                   |                        |                    |                 |
| Abdominal                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neurological   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Small organs (specify)        |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   |   |   |      |      |               |                   |                        |                    |                 |
| Cardiac                       |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transesophageal               |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Musculo-skeletal Superficial  |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments:

- Small organs: Thyroid, Breast, Testicle
- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 Radiological Devices  
 File Number

*K061437*

1061437

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

Transducer: 5-12 L50

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

| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   |   |   |      |      |               |                   |                        |                    |                 |
| Abdominal                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neurological   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Small organs (specify)        |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   |   |   |      |      |               |                   |                        |                    |                 |
| Cardiac                       |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transesophageal               |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   | P | P | P    | P    | P             | P                 |                        | P                  |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Musculo-skeletal Superficial  |                   | P | P | P    |      | P             | P                 |                        | P                  |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments:

- Small organs: Thyroid, Breast, Testicle
- Combined modes: B + M, B + PWD, Color Doppler + PWD, Amplitude Doppler + PWD

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Ingram*  
 Division Sign-Off

Prescription Use (Per 21 CFR 801.109)

Office of Reproductive, Abdominal,  
 Neurological Devices

1061437

K061437

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic

Transducer: 2 MHz Pen

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

| Clinical Application              | Mode of Operation |   |   |         |         |                  |                      |                              |                       |                    |
|-----------------------------------|-------------------|---|---|---------|---------|------------------|----------------------|------------------------------|-----------------------|--------------------|
|                                   | A                 | B | M | PW<br>D | CW<br>D | Color<br>Doppler | Amplitude<br>Doppler | Color<br>Velocity<br>Imaging | Combined<br>(specify) | Other<br>(specify) |
| Ophthalmic                        |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Fetal                             |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Abdominal                         |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Intraoperative (specify)          |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Intraoperative Neuro-<br>logical  |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Pediatric                         |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Small organs (specify)            |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Neonatal Cephalic                 |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Adult Cephalic                    |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Cardiac                           |                   |   |   | P       | P       |                  |                      |                              |                       |                    |
| Transesophageal                   |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Transrectal                       |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Transvaginal                      |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Transurethral                     |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Intravascular                     |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Peripheral Vascular               |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Laparoscopic                      |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Musculo-skeletal<br>Conventional  |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Musculo-skeletal Super-<br>ficial |                   |   |   |         |         |                  |                      |                              |                       |                    |
| Other (specify)                   |                   |   |   |         |         |                  |                      |                              |                       |                    |

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

Additional Comments: .....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Emilia Segura*  
 (Signature)

Prescription Use (Per 21 CFR 801.109)

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 (Signature)

K061437

*K061437*

Diagnostic Ultrasound Indications for Use Form

System: Sigma 5000 series, Imagic      Transducer: 8 MHz Pen

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

| Clinical Application          | Mode of Operation |   |   |      |      |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|------|------|---------------|-------------------|------------------------|--------------------|-----------------|
|                               | A                 | B | M | PW D | CW D | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                    |                   |   |   |      |      |               |                   |                        |                    |                 |
| Fetal                         |                   |   |   |      |      |               |                   |                        |                    |                 |
| Abdominal                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative (specify)      |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intraoperative Neurological   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Pediatric                     |                   |   |   |      |      |               |                   |                        |                    |                 |
| Small organs (specify)        |                   |   |   |      |      |               |                   |                        |                    |                 |
| Neonatal Cephalic             |                   |   |   |      |      |               |                   |                        |                    |                 |
| Adult Cephalic                |                   |   |   |      |      |               |                   |                        |                    |                 |
| Cardiac                       |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transesophageal               |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |      |      |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   |   |   | P    | P    |               |                   |                        |                    |                 |
| Laparoscopic                  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |      |      |               |                   |                        |                    |                 |
| Musculo-skeletal Superficial  |                   |   |   |      |      |               |                   |                        |                    |                 |
| Other (specify)               |                   |   |   |      |      |               |                   |                        |                    |                 |

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

Additional Comments: .....

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*[Signature]*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 File Number *K061437*