K050099

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

JAN 2 8 2005

1. Submitter Information

a. Submitter:	Kontron Medical SAS 52, rue Pierre Curie 78373 Plaisir, Yveline France
b. Contact Person:	Ms. Georgina Fabian Kontron Medical LLC. 9j Brookside Heights Wanaque, NJ 07465 Phone: 973-839-8669
c. Date Prepared:	15 September 2004

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

The Sigma 5000 series, Imagic is an ultrasound instrument intended to perform 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).

The submission also includes the transducers necessary for these procedures.

The system is a mobile console approximately 60 cm wide, 95 cm deep and 130 cm high equipped with a keyboard control panal, a large TFT screen, assorted transducers and image storage or hard-copy devices

5. Intended use

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

6. Performance Data

a. Non-clinical tests: The device has been evaluated for acoustic output, biocompatibility and thermal, electrical and mechanical safety, and has been found conform with applicable medical device safety standards.

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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 2 8 2005

Re: K050099
Trade Name: Sigma 5000 Series, Imagic Ultrasound System
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: 90 IYN, IYO, and ITX
Dated: January 17, 2005
Received: January 18, 2005

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 Ultrasound System, as described in your premarket notification:

Transducer Model Number

2-4 PA
2-5 CA

5-12 LA
3-8 PA
3-8 TEM
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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure(s)

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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		N	N	N		N	N		N	
Abdominal		N	N	N		N	N		N	
Intraoperative (specify)										
Intraoperative Neuro-logical										
Pediatric		N	N	N		N	N		N	
Small organs (specify)		N	N	N		N	N		N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N	
Transesophageal		N	N	N	N	N	N		N	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N	
Laparascopic										
Musculo-skeletal Conventional		N	N	N		N	N		N	
Musculo-skeletal Super-ficial		N	N	N		N	N		N	
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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050099

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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										
Cardiac		N	N	N	N	N	N		N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Super-ficial										
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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050099

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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		N	N	N		N	N		N	
Abdominal		N	N	N		N	N		N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050099

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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		N	N	N		N	N		N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	
Small organs (specify)		N	N	N		N	N		N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N	
Laparascopic										
Musculo-skeletal Conventional		N	N	N		N	N		N	
Musculo-skeletal Superficial		N	N	N		N	N		N	
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) Nancy C Brogdon

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

Prescription Use (Per 21 CFR 801.109)

510(k) Number K050089

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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		N	N	N	N	N	N		N	
Small organs (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Super-ficial										
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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050099

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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 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										
Cardiac		N	N	N	N	N	N		N	
Transesophageal		N	N	N	N	N	N		N	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Super-ficial										
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)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050099

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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 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				N	N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: .....

.....

.....

.....

.....

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050099

Kontron Medical
52, rue Pierre Curie
F-78373 Plaisir, Yvelines

KONTRON MEDICAL

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				N	N					
Laparascopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: .....

.....

.....

.....

.....

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050099

Prescription Use (Per 21 CFR 801.109)