



K964617

510(k) Summary of Safety and Effectiveness: GE LOGIQ 700 3D Cine

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact : D. Duersteler, Safety and Regulatory Programs
414-647-4385

Date Prepared: October 25, 1996

Product Identification: GE LOGIQ 700 Diagnostic Ultrasound System with 3D Cine.

Marketed Devices: The GE LOGIQ 700 Diagnostic Ultrasound System with 3D is of a comparable type and substantially equivalent to the GE Medical Systems LOGIQ 700 diagnostic ultrasound system, 510(k) Number K930768, currently in commercial distribution:

Device Description: The LOGIQ 700 diagnostic ultrasound system with 3D is the same in all other aspects as the currently marketed LOGIQ 700, consisting of a mobile console approximately 70 cm wide, 120 cm deep and 120 cm high that provides full 128 channel capability, and assorted transducers. The user interface is an adjustable height keyboard, small A/V display panel and a color video display monitor. Optional image storage or hard-copy devices are integrated into the design.

Indications for Use: LOGIQ 700 with 3D is a general purpose ultrasound imaging system intended for use by, or under the direction of, a qualified physician in the evaluation of soft tissue and vascular disease of the head, neck chest, abdomen pelvis, male and female reproductive organs, limbs and pregnant uterus of the adult, pediatric or neonatal patient.

Comparison with Predicate Device: The GE LOGIQ 700 with 3D is comparable in key safety and effectiveness features, uses the same design, construction, and materials, and has the same intended uses and operating modes as the predicate device.

Summary of Studies: The device has been evaluated for acoustic output, biocompatibility, and thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

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 GMP standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE LOGIQ 700 with 3D Cine 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

David Duersteler
Safety/Regulatory Project Engineer
GE Medical Systems
PO Box 414
Milwaukee, WI 53201

001 3

Re: K964617
Dated: August 25, 1997
Received: August 27, 1997
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYO

Dear Mr. Duersteler:

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 LOGIQ 700 with 3D View, as described in your premarket notification:

<u>Transducer Model Number</u>			
326s	618E	348C	LA39
547L	618C	227s	M3C
739L	548C	546L	M12L

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, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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.html>".

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

Sincerely yours,

Lillian Yin
for 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(s)

510(k) Number (if known): K964617
 Device Name: LOGIQ 700 326s Transducer

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

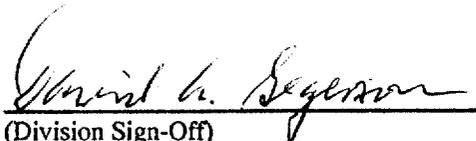
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal and other		X	X	X		X	X		X	
Abdominal		X	X	X		X	X		X	
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric			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

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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

510(k) Number K964617

510(k) Number (if known): K964617
 Device Name: LOGIQ 700 547L Transducer

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 and other		X	X	X		X	X		X	
Abdominal										
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric										
Small Organ (Specify)		X	X	X		X	X		X	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel		X	X	X		X	X		X	
Laparoscopic										

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617
 Device Name: LOGIQ 700 739L Transducer

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 and other		X	X	X		X	X		X	
Abdominal										
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric		X	X	X		X	X		X	
Small Organ (Specify)		X	X	X		X	X		X	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel		X	X	X		X	X		X	
Laparoscopic										

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Johnson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 618E Transducer

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 and other		X	X	X		X	X		X	
Abdominal										
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal		X	X	X		X	X		X	
Trans-vaginal		X	X	X		X	X		X	
Intra-luminal										
Trans-urethral										
Peripheral vessel										
Laparoscopic										

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segerson

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

510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 618C Transducer

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 and other										
Abdominal										
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric		X	X	X		X	X		X	
Small Organ (Specify)										
Neonatal Cephalic		X	X	X		X	X		X	
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel		X	X	X		X	X		X	
Laparoscopic										

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Segerson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617
 Device Name: LOGIQ 700 **548C** Transducer

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

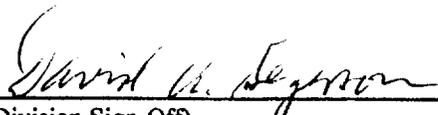
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal and other		X	X	X		X	X		X	
Abdominal		X	X	X		X	X		X	
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric			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

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 **348C** Transducer

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

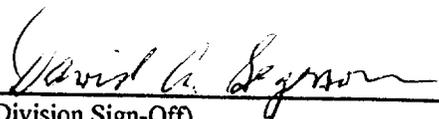
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal and other		X	X	X		X	X		X	
Abdominal		X	X	X		X	X		X	
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric			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

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 **227s** Transducer

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

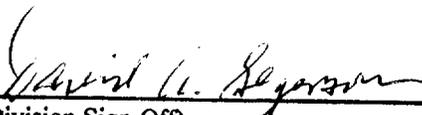
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal and other		X	X	X		X	X		X	
Abdominal		X	X	X		X	X		X	
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric			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

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 546L Transducer

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

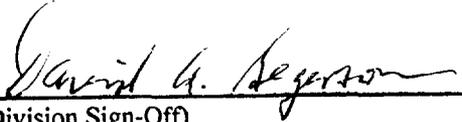
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal and other		X	X	X		X	X		X	
Abdominal										
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric									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

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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

510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 LA39 Transducer

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

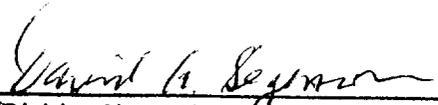
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal and other Abdominal		X	X	X		X	X		X	
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric		X	X	X		X	X		X	
Small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

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 M3C Transducer

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

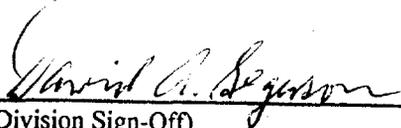
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal and other		X	X	X		X	X		X	
Abdominal		X	X	X		X	X		X	
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric			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

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617

510(k) Number (if known): K964617

Device Name: LOGIQ 700 **M12L** Transducer

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 and other		X	X	X		X	X		X	
Abdominal										
Musculoskeletal										
Intra-operative										
Neurosurgical										
Pediatric										
Small Organ (Specify)		X	X	X		X	X		X	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel		X	X	X		X	X		X	
Laparoscopic										

Other Indications or Modes: Small organ includes breast, testes, thyroid. Fetal and Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Edward G. Segerson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K964617