

SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

Device Generic Name : Ultrasonic pulsed echo imaging system and ultrasonic transducers
Ultrasonic pulsed Doppler imaging system

Device Trade Name : AspenTM Ultrasound System with FreeStyleTM Imaging Option

510k No : Unknown at this time

Date of 510k Submission : May 24,1999

II. INDICATIONS FOR USE

The Aspen Ultrasound System with the FreeStyle option provides B-mode images of anatomy in a field of view that extends well beyond a conventional B-mode region of interest. The FreeStyle option can also provide qualitative Color flow information in this extended field of view. The indications for use for each transducer operating with the FreeStyle feature are unchanged and include fetal, small organ, peripheral vessel, abdominal, gynecologic, transrectal, intraoperative, and musculoskeletal uses.

III. DEVICE DESCRIPTION

The Aspen Ultrasound System with the FreeStyle feature is a modification of the Aspen Ultrasound System previously cleared as Model 2001, K934915/S1. The FreeStyle feature allows visualization of anatomy over a wider field of view that surrounds a particular region of interest. The feature operates in B-mode and Color Doppler modes for transducers that have been previously cleared by FDA for all indications for use except cardiac, ophthalmic, and transcranial uses.

The FreeStyle feature operates by collecting a series of B-mode or Color Doppler image frames in real time, storing them, and then forming a larger composite image for display. The composite image can be displayed within seconds of the real time image frame captures or can be stored and displayed at a later time, perhaps at a Picture Archiving and Communications (PACS) review station. The frames can be captured over a 70cm linear distance or less.

The process is executed by a Pentium II or III based PC running Windows NT that is cabled to the ultrasound system and which resides on a shelf in the ultrasound system console. The hardware and software of the ultrasound system itself has not been modified except to add keyboard strokes that enables the Freestyle option and transfers control between the PC and ultrasound system. The PC has been programmed to store the B mode and Color Doppler image frames captured by the ultrasound system in DICOM format, to perform 2 dimensional motion analysis to determine frame to frame translation and rotation vectors, to form the composite extended image using a graphics library function, and to transfer the extended image back to the ultrasound system for display or storage.

There is also a caliper measurement capability in the PC software that can be used on the B mode extended images to perform distance and length measurements. The Color Doppler extended images are used to detect the presence or absence of blood flow and are not for quantification.

IV. WARNINGS AND PRECAUTIONS

The addition of the FreeStyle feature resulted in modifying our labeling to include the following warnings and cautions:

Caution: Your judgement as a trained sonographer or physician is required to determine if the following artifactual characteristics exist. The presence of these artifacts make the quality of an image suspect and may require reacquisition.

- Obvious linear discontinuity is normally related to a jerky motion during acquisition or moving out of plane. Discontinuity related lines are usually perpendicular to the transducer face.
- Excess shadowing will make the motion estimation process unreliable.
- Ill defined anatomy or evidence of distorted anatomical representation.
- Jagged skin line.

Warning: An unreliable caliper measurement can be caused by the following sources of error:

- Wrong B-mode Slice – When attempting to measure the maximum length within a 3D organ remember that you are only measuring from a 2D slice within that organ. Repeat the scan until you are certain that you have the slice most relevant to a possible diagnosis.
- Non planar acquisition – FreeStyle imaging (like similar ultrasound image composition products) assumes that the acquisition lies in a single flat plane. If acquisition follows a curve, then an unwrapped image is formed.

Warning: In the case of a poorly reconstructed FreeStyle image, as determined by the above criteria or by the user's clinical experience and training, dimensional measurements should not be made. If for any reason measurements are made using a poorly reconstructed image, these measurements should not be used for making diagnostic decisions.

The user must satisfy themselves of the accuracy of image representations and measurements. FreeStyle image scans should be repeated if there is the slightest doubt as to the accuracy of images and measurements.

Important: When it is possible to make a measurement on a single acquired image frame, then that is preferable. Only make measurements when you are satisfied that the reconstructed image is free from acquisition related artifacts.

V. POTENTIAL ADVERSE EFFECTS

Misdiagnosis caused by inaccurate measurements and calculations made on poorly reconstructed FreeStyle images is a potential adverse effect introduced by the addition of the FreeStyle feature.

Since this a user dependent effect the risk of this adverse effect occurring can only be mitigated by warnings in the labeling and adequate training.

VI. BIOCOMPATIBILITY

No changes to materials that could possibly contact patients and users have been made. A matrix of biocompatibility data for existing patient contact materials is on file.

VII. IMAGING PERFORMANCE

Clinical data was obtained to show the efficacy of FreeStyle images. They are contained in the 510k and were reviewed by FDA.



AUG - 2 1999

AUG - 4 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William Welch
Manager, Regulatory Affairs
Acuson Corporation
1220 Charleston Road
P.O. Box 17393
Mountain View, California 94043-7393

Re: K991805
Trade Name: Aspen™ Ultrasound System with FreeStyle™ Imaging Option
Regulatory Class: II
Product Code: 21 CFR 892.1550/Procode: 90-IYN, Ultrasonic Pulsed Doppler Imaging System
21 CFR 892.1560/Procode: 90-IYO, Ultrasonic Pulsed Echo Imaging System
21 CFR 892.1570/Procode: 90-ITX, Diagnostic Ultrasound

Dated: May 24, 1999
Received: May 26, 1999

Dear Mr. Welch:

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 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 Aspen™ Ultrasound System with FreeStyle™ Imaging Option, as described in your premarket notification:

Transducer Model Number

4V2, C3, C7, EVC8, L582, V328, V4, V5, V7, 4V1, 5C2, L10, EC7, ER7B, EV7, L5, L7, L7L, L7T, S219R

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

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Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

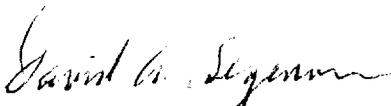
Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976,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

This 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 Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for 

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Aspen Ultrasound System

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | * | |
| Abdominal | | P | P | P | | P | P | | * | |
| Intra-operative (Specify) | | P | P | P | | P | P | | * | |
| Intra-operative Neurological | | P | P | P | | P | P | | * | |
| Pediatric | | P | P | P | | P | P | | * | |
| Small Organ - Thyroid - Breast - Testicle | | P | P | P | | P | P | | * | |
| Neonatal Cephalic | | P | P | P | | P | P | | * | |
| Adult Cephalic | | P | P | P | | P | P | | * | |
| Cardiac | | P | P | P | | P | P | | * | |
| Trans-esophageal | | P | P | P | | P | P | | * | |
| Trans-Rectal | | P | P | P | | P | P | | * | |
| Trans-Vaginal | | P | P | P | | P | P | | * | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | P | P | | * | |
| Laparoscopic | | P | P | P | | P | P | | * | |
| Musculo-Skeletal Conventional | | P | P | P | | P | P | | * | |
| Musculo-Skeletal Superficial | | P | P | P | | P | P | | * | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

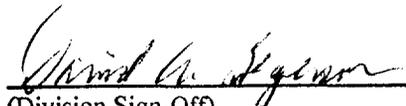
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: 4V2

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | E | E | E | | E | E | | * | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

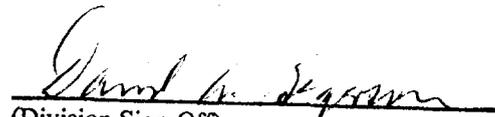
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E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: C3

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | E | E | E | | E | E | | * | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR FORM

Ultrasound System: Aspen

Transducer: C7

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | E | E | E | | E | E | | * | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | E | E | E | | E | E | | * | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: EVC8

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | E | E | E | | E | E | | * | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

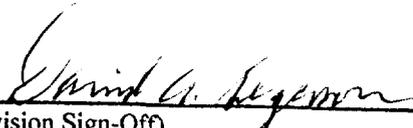
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: L582

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | * | |
| Abdominal | | P | P | P | | P | P | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | 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:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Division of Reproductive, Abdominal, ENT,
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 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: V328

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | * | |
| Abdominal | | P | P | P | | P | P | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

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E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Berger
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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: V4

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

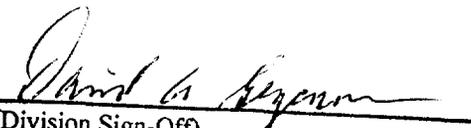
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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

Ultrasound System: Aspen

Transducer: V5

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | E | E | E | | E | E | | * | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

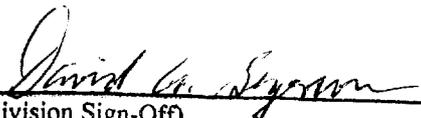
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K 991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: V7

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | P | P | | P | P | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | * | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| 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:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

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 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: 4V1

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| 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:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: 5C2

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | E | E | E | | E | E | | * | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

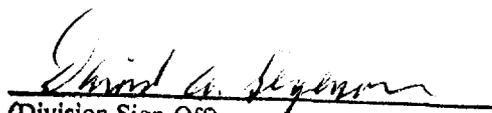
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: L10

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | E | E | E | | E | E | | * | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | E | E | E | | E | E | | * | |
| Musculo-Skeletal Superficial | | E | E | E | | E | E | | * | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

*Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use
 (Per 21 CFR 801.109)

K 991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: EC7

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | E | E | E | | E | E | | * | |
| Trans-Vaginal | | E | E | E | | E | E | | * | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| 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:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


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 and Radiological Devices
 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: ER7B

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | E | E | E | | E | E | | * | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

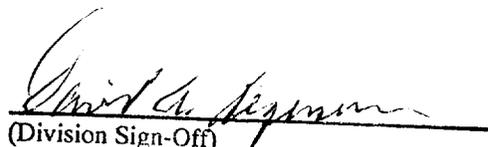
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


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 Division of Reproductive, Abdominal, ENT,
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510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: EV7

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | E | E | E | | E | E | | * | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | E | E | E | | E | E | | * | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| 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:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: L5

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | * | |
| Abdominal | | P | P | P | | P | P | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | P | P | | * | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

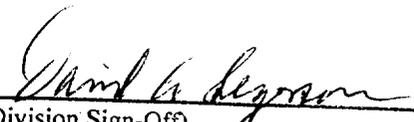
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


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 Division of Reproductive, Abdominal, ENT,
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 510(k) Number K991805

Prescription Use
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: - Aspen

Transducer: L7

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | P | P | | P | P | | * | |
| Intra-operative - abdominal - cardiac | | P | P | P | | P | P | | * | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | P | P | P | | P | P | | * | |
| Neonatal Cephalic | | P | P | P | | P | P | | * | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | | P | P | | * | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | P | P | P | | P | P | | * | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | P | P | P | | P | P | | * | |
| Musculo-Skeletal Superficial | | P | P | P | | P | P | | * | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

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 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: L7L

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | E | E | E | | E | E | | * | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication P = Previously cleared by FDA E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use _____
 (Per 21 CFR 801.109) 510(k) Number K991805

K991805

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: L7T

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | E | E | E | | E | E | | * | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

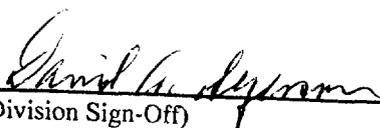
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
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 510(k) Number K991805

Prescription Use _____
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Ultrasound System: Aspen

Transducer: S219R

| Clinical Applications | A | B | M | PWD | CWD | Color Doppler | Power (Ampl.) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|--|---|---|---|-----|-----|---------------|-----------------------|------------------------|--------------------|-----------------|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | E | E | E | | E | E | | * | |
| Intra-operative (Specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ - Thyroid - Breast - Testicle | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

N = New Indication

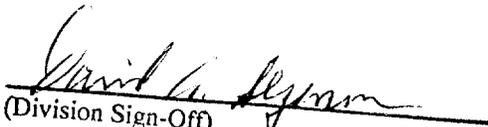
P = Previously cleared by FDA

E = Added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K991805