



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 8 2009

The Newman Group, LLC  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K090465  
Trade/Device Name: DigiDop Ultrasound System  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: ITX and LXE  
Dated: March 24, 2009  
Received: March 25, 2009

Dear Mr. Job:

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 DigiDop Ultrasound System, as described in your premarket notification:

Transducer Model Number

2MHz

3MHz

5MHz

8MHz

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.

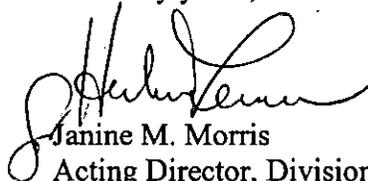
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact John Chen at (240) 276-3666.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

K090465

### Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Product Name: DigiDop Main Unit with either a nominal 2, 3, 5, or 8 MHz continuous wave probe. Nominal 2 and 3MHz probes are intended for fetal heart beat detection. Nominal 5 and 8 MHz probes are intended for peripheral vascular diagnosis.

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

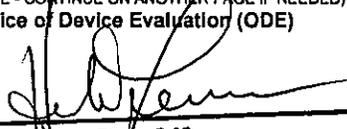
| Clinical Application          | Mode of Operation |   |   |     |     |               |                   |                        |                    |                 |
|-------------------------------|-------------------|---|---|-----|-----|---------------|-------------------|------------------------|--------------------|-----------------|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

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

Additional Comments: The system consists of a main body and one probe. The nominal 2 or 3 MHz probes are designed for fetal applications. The nominal 5 or 8MHz probes are designed for peripheral vascular applications.

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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,  
and Radiological Devices

510(k) Number

K090465

K090465

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Product Name: DigiDop 2MHz

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

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

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

Additional Comments: The nominal 2MHz probe is intended for fetal applications.

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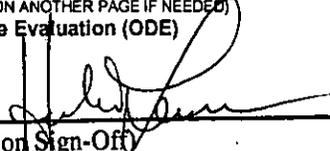
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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K090465

K090465

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Product Name: DigiDop 3MHz

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

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

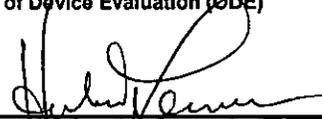
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The nominal 3MHz probe is intended for fetal applications

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
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 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K090465

K090465

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Product Name: DigiDop 5MHz

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

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

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

Additional Comments: The nominal 5MHz probe is intended for peripheral vascular applications.

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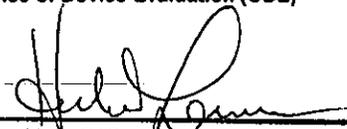
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Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K090465

K090465

### Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Product Name: DigiDop 8MHz

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

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

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

Additional Comments: The nominal 8MHz probe is intended for peripheral vascular applications.

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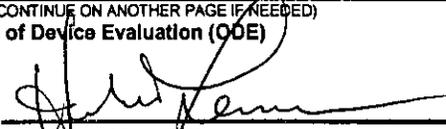
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Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K090465