



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2016

The Prometheus Group
% Mr. Joshua Bird
Senior Software Engineer
1 Washington Street, Suite 303
DOVER NH 03820

Re: K160792

Trade/Device Name: Morpheus[®] RealTime Ultrasound, Pathway[®] RealTime Ultrasound,
QuickScan[®] Bladder Ultrasound

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYO, ITX

Dated: March 25, 2016

Received: March 29, 2016

Dear Mr. Bird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A large, semi-transparent "FDA" watermark is visible behind the signature.

FOR

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160792

Device Name

Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound

Indications for Use (Describe)

Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound are diagnostic ultrasound systems designed to be used for general pelvic imaging. An ultrasonographic crystal within the probe records images of the organ, muscle, and tissue structures of the pelvic region. Measurements and calculations of the organ, muscle, and tissue structures can be recorded.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Diagnostic Ultrasound Indications for Use

System: The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	N						Note 2 Note 3
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N						Note 3
	Trans-vaginal	N						
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Other (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication

Note 1: Abdominal - Pelvic, Solid Organs, Aneurysms, Bladder

Note 2: Small Organ - Testes, Prostate

Note 3: Includes imaging for guidance of biopsy.

Prescriptive Use (Part 21 CFR 801.109)

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

Concurrence of CDRH

510(k) Premarket Notification
 The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound,
 QuickScan® Bladder Ultrasound

Diagnostic Ultrasound Indications for Use

System: The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound

Transducer: GP 3.5 MHz / AB 3.5 MHz Mechanical Sector Probe

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						Note 2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Other (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

P = previously cleared by FDA, K070907

Note 1: Abdominal - Pelvic, Solid Organs, Aneurysms, Bladder

Note 2: Small Organ - Testes, Prostate

Prescriptive Use (Part 21 CFR 801.109)

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Concurrence of CDRH

510(k) Premarket Notification
 The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound,
 QuickScan® Bladder Ultrasound

Diagnostic Ultrasound Indications for Use

System: The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound

Transducer: ER 12 MHz / ES 12 MHz Mechanical Sector Probe

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal		P					
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

P = previously cleared by FDA, K070907

Prescriptive Use (Part 21 CFR 801.109)

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Concurrence of CDRH

510(k) Premarket Notification
 The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound,
 QuickScan® Bladder Ultrasound

Diagnostic Ultrasound Indications for Use

System: The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound

Transducer: EC 7.5 MHz / EB 7.5 MHz Mechanical Sector Probe

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		P						Note 3
	Trans-vaginal		P						
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

P = previously cleared by FDA, K070907

Note 3: Includes imaging for guidance of biopsy.

Prescriptive Use (Part 21 CFR 801.109)

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Concurrence of CDRH

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

Submitter's name, address, telephone number, contact person:

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Prepared February 26, 2016

Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound

Classification Names:

	<u>CFR Number</u>	<u>Product Code</u>
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Predicate Device:

Device Name:

Interson USB Ultrasound Probe System

Manufacturer:

Interson Corporation

510(k) Number:

K070907

The Prometheus Group® believes that Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound are substantially equivalent to the currently marketed Interson USB Ultrasound Probe System. The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound have the same technological characteristics, safety and effectiveness features, comparable intended uses, and basic operating modes.

Device Description:

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound utilize the ultrasound probes, cable and host software application used in Interson USB Ultrasound Probe System. The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound are a self contained portable, multiple-mode, and multiple-application ultrasound imaging system. The system contains an ultrasound generator/receiver, analog to digital converter, microcontroller, control logic, USB 2.0 interface and control offering a full complement of conventional operating modes, software-based parameter controls, and video recording.

User-customized parameter settings for the Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound may be inserted by the operator and stored for recall as needed via the system control panel.

Customization includes transmit power, images controls selection, and Time Gain Compensation (TGC). Controls are also provided to select display format and to utilize the cine function.

510(k) Premarket Notification

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound

Patient contact materials have been used in accordance to their intended use and are described below for each individual transducer. The transducers were previously cleared for use on other Systems (K070907).

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound are a B-Mode ultrasound scanner, which provides high resolution, high penetration performance. Probes are supported in frequencies from 2.5 MHz to 12.0 MHz.

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound provides various measuring functions. It can measure distances and calculate areas, circumferences and volumes, and calculate angles. The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound supports the Cine function (capable of storing up to 512 sequential images). Management of patient history is possible by image-storage function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing. The same clinical uses were cleared for the predicate device Interson USB Ultrasound Probe System, K070907.

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound interfaces with the Interson USB Ultrasound Probe System software to collect the ultrasound images, measurements, and calculations. The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound allows for the entry of patient information and generates reports from the recorded ultrasound images, measurements, and calculations.

Morpheus® RealTime Ultrasound

The Prometheus Group® Morpheus® RealTime Ultrasound allows the user to select up to 10 ultrasound images from an exam to include in the report. Additionally the user can input notes on the exam which are also included in the report. The report is formatted to be printed on standard 8 1/2" X 11" paper.

Pathway® RealTime Ultrasound

The Prometheus Group® Morpheus® RealTime Ultrasound allows the user to select up to 10 ultrasound images from an exam to include in the report. Additionally the user can input notes on the exam which are also included in the report. The report is formatted to be printed on standard 8 1/2" X 11" paper.

QuickScan® Bladder Ultrasound

The Prometheus Group® QuickScan® Bladder Ultrasound generates a condensed report containing a single image with the measurements and calculations recorded during the exam. The report is formatted to be printed on 80 mm thermal printer paper.

Indications for Use:

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound are diagnostic ultrasound systems designed to be used for general pelvic imaging. An ultrasonographic crystal within the probe records images of the organ, muscle, and tissue structures of the pelvic region. Measurements and calculations of the organ, muscle, and tissue structures can be recorded.

Comparison of Technological Characteristics with the Predicate Device:

Technological Characteristics		Subject Device: The Prometheus Group® Morpheus® RealTime Ultrasound	Subject Device: The Prometheus Group® Pathway® RealTime Ultrasound	Subject Device: The Prometheus Group® QuickScan® Bladder Ultrasound	Predicate Device: Interson USB Ultrasound Probe System (K070907)
Materials	Lens	TPX brand Polymethyle Pentene (PMP)	TPX brand Polymethyle Pentene (PMP)	TPX brand Polymethyle Pentene (PMP)	TPX brand Polymethyle Pentene (PMP)
	Housing	Ertalyte brand Polyethylene Terephthalate (PET-P), Delrin	Ertalyte brand Polyethylene Terephthalate (PET-P), Delrin	Ertalyte brand Polyethylene Terephthalate (PET-P), Delrin	Ertalyte brand Polyethylene Terephthalate (PET-P), Delrin
Measurements		Distance (mm), Circumference (mm), Area (mm ²), Angle (degree)	Distance (mm), Circumference (mm), Area (mm ²), Angle (degree)	Distance (mm), Circumference (mm), Area (mm ²), Angle (degree)	Distance (mm), Circumference (mm), Area (mm ²), Angle (degree)
Report		Multiple page report displaying up to 10 user selectable images. The report also displays notes entered into the system by the user. Printed on standard 8 1/2" X 11" paper.	Multiple page report displaying up to 10 user selectable images. The report also displays notes entered into the system by the user. Printed on standard 8 1/2" X 11" paper.	Single page report displaying a single image. Printed on 80mm thermal printer paper.	Single page report displaying the first four saved images. Printed on standard 8 1/2" X 11" paper.
Principle Operation		Apply high voltage bursts to Piezoelectric material in the transducer and detect the reflected echo to construct 2D images for diagnostic purposes.	Apply high voltage bursts to Piezoelectric material in the transducer and detect the reflected echo to construct 2D images for diagnostic purposes.	Apply high voltage bursts to Piezoelectric material in the transducer and detect the reflected echo to construct 2D images for diagnostic purposes.	Apply high voltage bursts to Piezoelectric material in the transducer and detect the reflected echo to construct 2D images for diagnostic purposes.

510(k) Premarket Notification

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, QuickScan® Bladder Ultrasound

Technological Characteristics	Subject Device: The Prometheus Group® Morpheus® RealTime Ultrasound	Subject Device: The Prometheus Group® Pathway® RealTime Ultrasound	Subject Device: The Prometheus Group® QuickScan® Bladder Ultrasound	Predicate Device: Interson USB Ultrasound Probe System (K070907)
Transducer Probe Design	Mechanical sector ultrasound imaging probe that connects directly to host computer via Universal Serial Bus (USB). Host computer forms real-time ultrasonic images of human tissue without need for additional electronics, power supplies, or support devices of any kind.	Mechanical sector ultrasound imaging probe that connects directly to host computer via Universal Serial Bus (USB). Host computer forms real-time ultrasonic images of human tissue without need for additional electronics, power supplies, or support devices of any kind.	Mechanical sector ultrasound imaging probe that connects directly to host computer via Universal Serial Bus (USB). Host computer forms real-time ultrasonic images of human tissue without need for additional electronics, power supplies, or support devices of any kind.	Mechanical sector ultrasound imaging probe that connects directly to host computer via Universal Serial Bus (USB). Host computer forms real-time ultrasonic images of human tissue without need for additional electronics, power supplies, or support devices of any kind.
Acoustic Output Limits: All Applications	¹SPTA.3 94 mW/cm ² (Max) MI 1.9 (Max)			
Clinical Applications	Abdomen OB/GYN Urology	Abdomen OB/GYN Urology	Abdomen OB/GYN Urology	Abdomen OB/GYN Urology Cardiac Fetal Heart Vascular Pediatric Neonatal Cephalic Ophthalmology Extremity

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound utilize the ultrasound probes, cable, and host software application, which were previously cleared under K070907. These devices operate identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D images.

The technological differences in clinical applications indicated for The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound systems versus those indicated for the Interson USB Ultrasound Probe System do not raise concerns for the safety and effectiveness of the device because the clinical applications indicated for The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound systems are a subset of the clinical applications indicated for the Interson USB Ultrasound Probe System. The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound system does not indicate any clinical applications outside of those indicated for the Interson USB Ultrasound Probe System. Additionally the clinical applications indicated for The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound are independent of the clinical applications not indicated.

Morpheus® RealTime Ultrasound

The technological differences in the report The Prometheus Group® Morpheus® RealTime Ultrasound do not raise concerns for the safety and effectiveness of the device because the images and data displayed in The Prometheus Group® Morpheus® RealTime Ultrasound report would also be displayed in the Interson USB Ultrasound Probe System report. The ability to include more images and user notes on the exam in the report by The Prometheus Group® Morpheus® RealTime Ultrasound increase the effectiveness of the report by allowing the user to provide more evidence to substantiate the findings of the exam.

Pathway® RealTime Ultrasound

The technological differences in the report The Prometheus Group® Pathway® RealTime Ultrasound do not raise concerns for the safety and effectiveness of the device because the images and data displayed in The Prometheus Group® Pathway® RealTime Ultrasound report would also be displayed in the Interson USB Ultrasound Probe System report. The ability to include more images and user notes on the exam in the report by The Prometheus Group® Pathway® RealTime Ultrasound increase the effectiveness of the report by allowing the user to provide more evidence to substantiate the findings of the exam.

QuickScan® Bladder Ultrasound

The technological differences in the report The Prometheus Group® QuickScan® Bladder Ultrasound do not raise concerns for the safety and effectiveness of the device because the images and data displayed in The Prometheus Group® QuickScan® Bladder Ultrasound report would also be displayed in the Interson USB Ultrasound Probe System report. The ability to include more images and user notes on the exam in the report by The Prometheus Group® QuickScan® Bladder Ultrasound would provide the same evidence to substantiate the findings as the Interson USB Ultrasound Probe System.

Nonclinical Tests and Standards Used:

The nonclinical tests performed on the Interson USB Ultrasound Probe System for clearance under 510(k) K070907 are applicable to The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound as the Interson USB Ultrasound Probe System has not been modified by The Prometheus Group®.

Clinical Tests:

The Prometheus Group® Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound did not require clinical studies to support substantial equivalence.

Conclusion:

The Prometheus Group® considers the Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound devices to be as safe and effective as the predicate device. The performance of the subject device is substantially equivalent to the predicate device.

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 medical device industry standards. The device conforms to 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 The Prometheus Group® that the Morpheus® RealTime Ultrasound, Pathway® RealTime Ultrasound, and QuickScan® Bladder Ultrasound are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.