DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 7, 2017

WinProbe Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K173265
Trade/Device Name: UltraVision 2 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 25, 2017
Received: October 26, 2017

Dear Mr. Job:

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,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173265

Device Name
UltraVision 2 Diagnostic Ultrasound System

Indications for Use *(Describe)*
This diagnostic ultrasound system (UltraVision) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients, (thyroid, breast, and testicles) and for peripheral vessel, abdominal, and superficial muscular skeletal diagnosis.

The system is for prescription use only by a trained sonographer under the direction of a qualified physician or directly by a qualified physician.

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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Indications for Use Table (system)

System: UltraVision 2 Diagnostic Ultrasound System

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Intra-operative (specify)							
	Intra-operative (neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify) Breast, Thyroid, Testes	P	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-cardiac)							
	Musculo-skeletal (conventional)							
	Musculo-skeletal (superficial)	P	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N(B+M), N(B+Color) N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Other (specify)							

N = new indication; P= previously cleared by FDA 510(k)150580. **Notes:** [1]Elastography (E-Mode)

Indications for Use Table (transducer)

Transducer: HL5-10EPN transducer for use with UltraVision 2

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Intra-operative (specify)							
	Intra-operative (neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify) Breast, Thyroid, Testes	P	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-cardiac)							
	Musculo-skeletal (conventional)							
	Musculo-skeletal (superficial)	P	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N(B+M), N(B+Color) N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Other (specify)							

N = new indication; P= previously cleared by FDA 510(k) 150580 **Notes:** [1]Elastography (E-Mode)

Indications for Use Table (transducer)

Transducer: L14-4 transducer for use with UltraVision 2

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Intra-operative (specify)							
	Intra-operative (neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify) Breast, Thyroid, Testes	N	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-cardiac)							
	Musculo-skeletal (conventional)							
	Musculo-skeletal (superficial)	N	N	N		N	N(B+M), N(B+Color), N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N(B+M), N(B+Color) N (B+E), N(B+PW) N(B+PW+color)	N[1]
	Other (specify)							

N = new indication; **Notes:** [1]Elastography (E-Mode)

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K173265

Submitter

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Date Prepared:

September 28th, 2017

Device Name and Classification:

Common/Usual Name:

Diagnostic Ultrasound System

Proprietary Name:

UltraVision 2 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN

Predicate Device:

Siemens Acuson S2000 Ultrasound System, K142876

Device Description:

The UltraVision 2 is a portable Diagnostic Ultrasound System which applies the latest technologies to produce optimal images. Various image parameter adjustments, a 15 inch high resolution display, and custom probes are configured to provide clear and stable images. It operates in B-mode, M-Mode, Color Flow Doppler Mode, Pulsed Wave Doppler Mode, and E-Mode.

Intended Use:

This diagnostic ultrasound system (UltraVision) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients, (thyroid, breast, and testicles) and for peripheral vessel, abdominal, and superficial muscular skeletal diagnosis.

The system is for prescription use only by a trained sonographer under the direction of a qualified physician or directly by a qualified physician.

Comparison to the predicate device:

The UltraVision 2 diagnostic ultrasound system uses the same fundamental scientific technologies as the predicate device (Siemens Acuson S2000, K142876). Table 1 compares the UltraVision 2 to the predicate device with respect to indications for use, intended use, and principles of operation for the determination of substantial equivalence. The table also compares the system to the previously cleared system.

	UltraVision 2	Acuson S2000	UltraVision 2 (as cleared by k150580)
Description	The UltraVision is a portable Diagnostic Ultrasound System, which applies the latest technologies to produce optimal images. The system facilitates a workflow from image acquisition through to archival in a standard DICOM interface to the clinics PACs system. Various image parameter adjustments, a 15 inch high resolution display and custom probes are configured to provide clear and stable images. It operates in B, M, Color Flow Doppler, PW Doppler Mode, and E mode.	The ultrasound systems are multi-purpose mobile, software controlled diagnostic ultrasound systems with and on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. The function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude, Doppler Mode, a combination of modes, or Harmonic Imaging and 3D/4D Imaging on a Flat Panel Display.	The UltraVision is a portable Diagnostic Ultrasound System, which applies the latest technologies to produce optimal images. The system facilitates a workflow from image acquisition through to archival in a standard DICOM interface to the clinics PACs system. Various image parameter adjustments, a 15 inch high resolution display and custom probes are configured to provide clear and stable images. It operates in B mode.
Intended Use	This diagnostic ultrasound system (UltraVision) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients, (thyroid, breast, and testicles) and for peripheral vessel, abdominal, and superficial muscular skeletal diagnosis.	The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic,	This diagnostic ultrasound system (UltraVision) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients, (thyroid, breast, and testicles) and for superficial muscular skeletal diagnosis.

		cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the “ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging”. The Acuson	

		Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients	
Power Supply			
Voltage	90-264 V AC	90-264 V AC	90-264 V AC
Frequency	50/60 Hz	50/60 Hz	50/60 Hz
Operation Characteristic			
Installation and use	a. Portable equipment b. Mobile equipment (when installed on the mobile cart)	Mobile equipment	a. Portable equipment b. Mobile equipment (when installed on the mobile cart)
Mode of operation	Continuous operation	Continuous operation	Continuous operation
Physical Specifications			
Dimensions	400 mm (W) x 50 mm (H) x 250 mm (D)	623 mm (W) x 1300 mm (H) x 1103 mm (D)	400 mm (W) x 50 mm (H) x 240 mm (D)
Weight	4.5 kg	166 kg	4.5 kg
Temperature			
Operating:	0°C to 40°C	10°C to 40°C	0°C to 40°C
Transport/Storage:	Equipment should not be subject to excessive temperatures during transportation/storage	-20°C to 60°C	Equipment should not be subject to excessive temperatures during

			transportation/storage
Relative Humidity			
Operating:	Equipment should not be used in locations of high humidity	10% to 80%	Equipment should not be used in locations of high humidity
Transport/Storage:	Equipment should not be used in locations of high humidity	10% to 95%	Equipment should not be used in locations of high humidity
Safety Classifications			
Type of protection against electric shock	Class II	Class I	Class II
The degree of protection against electric shock	Type BF	Type BF	Type BF
The degree of protection against the harmful ingress of liquid	IP41 for the main unit IPX8 for the transducer	Ordinary equipment IPX8 for the transducers	IP41 for the main unit IPX8 for the transducer
The degree of safety of application in the presence of a flammable gas	Equipment not to be used in the presence of a flammable gas	Equipment not to be used in the presence of a flammable gas	Equipment not to be used in the presence of a flammable gas
Electrical & Mechanical Safety & Thermal Safety Standards			
The electrical, mechanical, and thermal safety evaluation	Complies with the standard: IEC 60601-1: 2007 IEC 60601-2-37: 2008	Complies with the standard: IEC 60601-1: 2007 IEC 60601-2-37: 2008	Complies with the standard: IEC 60601-1: 2007 IEC 60601-2-37: 2008

EMC evaluation	Complies with the standard: IEC 60601-1-2 4th edition	Complies with the standard: IEC 60601-1-2	Complies with the standard: IEC 60601-1-2 3rd edition
Acoustic output evaluation	Complies with the standard: IEC 61157 AIUM/NUMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound	Complies with the standard: IEC 61157 AIUM/NUMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound	Complies with the standard: IEC 61157 AIUM/NUMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
Biocompatibility evaluation	Complies with the standard: ISO 10993-1: 2009 ISO 10993-5: 2009 ISO 10993-10: 2009	Complies with the standard: ISO 10993-1: 2009 ISO 10993-5: 2009 ISO 10993-10: 2009	Complies with the standard: ISO 10993-1: 2009 ISO 10993-5: 2009 ISO 10993-10: 2009
Disinfection			
Disinfection	Probe: .55% Ortho Phthalaldehyde, 2.4% Glutaraldehyde	Probe: .55% Ortho-Phthalaldehyde 2.4% Glutaraldehyde	Probe: .55% Ortho Phthalaldehyde, 2.4% Glutaraldehyde
Specifications			
Monitor	15 inch display LCD flat panel display with 2800 x 1800 pixels	19 inch high-resolution flat panel display	15 inch display LCD flat panel display with 2800 x 1800 pixels
General imaging mode	B mode, M mode, E mode, Color flow dopper mode, shear mode	B mode, M mode, PWD mode, Color mode, CWD mode, eSie Touch™, Virtual Touch™	B mode
Scanning method	Linear	Linear, Rocked, Auto-sweep, STIC (Spatial Temporal Imaging Correlation)	Linear
Focus number	Max=4		Max=4
B mode general	Distance	Distance/Depth, Volume	Distance

measurements		and Stenosis, Area, Volume Flow, Circumference	
M mode general measurements	Distance, Time	Distance, Heart Rate, Slope, Time	/
D mode general measurements	/	Measurements on a frozen or CINE image including velocity/frequency, HR (Heart Rate), S/D (systolic/diastolic) ratio, RI (resistive index), PI (pulsatility index), TAMx (time-average maximum), TAMn (time-average mean), Slope (acceleration/deceleration), volume flow, A/B ratios, Time	/
Color Flow Doppler Mode general measurements	Distance	Measurements on a frozen or CINE image including velocity/frequency, HR (heart rate), S/D (systolic/diastolic ratio), RI (resistive index), PI (pulsatility index), TAMx (time-average maximum), TAMn (time-average mean), Slope (Acceleration/Deceleration), Volume Flow, A/B ratios, Time	/
PW Doppler Mode general measurements	Velocity	Measurements on a frozen or CINE image including velocity/frequency, HR (heart rate), S/D (systolic/diastolic ratio), RI (resistive index), PI (pulsatility index), TAMx (time-average maximum),	/

		TAMn (time-average mean), Slope (Acceleration/Deceleration), Volume Flow, A/B ratios, Time	
E Mode/eSie Touch™ general measurements	Provides a qualitative representation of relative tissue stiffness for the region of interest	Provides a qualitative representation of relative tissue stiffness for the region of interest	/
Shear Mode/Virtual Touch™ Mode general measurements	/	Use Virtual Touch tissue quantification to measure tissue shear velocity (Vs) for a selected region of interest. Virtual Touch quantification uses acoustic radiation force impulse (ARFI) technology of diagnostic ultrasound to induce tissue displacement. A time-controlled sequence of "push pulses" from the transducer induces a small displacement of tissue. The ultrasound system measures shear wave velocity at the region of interest	/
Peripheral Devices Supported			
Printer	Sony type UPD25MD (USB) color video printer	Black and white Mitsubishi printer P-93DW, color Sony printer UP-D23MD	Sony type UPD25MD (USB) color video printer
Performance			
Displayed depth	20 mm to 300 mm	.5 cm to 30 cm	20 mm to 300 mm
Gray scales	256	256	256

TGC	8 segments		8 segments
Image Adjustments			
B mode parameters	Gain	Gain	Gain
	Depth	Gray scale map	Depth
	TGC	SieClear spatial compounding	TGC
	Frequency	Edge enhancement	Frequency
	/	Tint/balance	/
	/	Level of clarify vascular enhancement	/
	/	Gray scale or color map for elasticity imaging	/
M mode parameters	Gain	Gain	/
	Map	Map	/
	/	Tint	/
	Transmit Frequency	Transmit frequency	/
Color mode & Power Doppler mode & Directional Power mode parameters	Transmit Frequency	Transmit frequency	/
	Gain	Gain	/
	Persistence	Persistence	/
	Pulsed repetition frequency	Pulsed repetition frequency	/

	Smoothing	Smoothing	/	
	Map	Map	/	
Measurement Accuracy				
2D Measurement				
Depth/Distance	Range	400 mm	34 cm	400 mm
	Accuracy	5%	5%	5%

Table 1. Predicate Device Comparison

Intended Use:

The intended use and clinical applications of the UltraVision 2 system are narrowed, but still in the scope of the predicate device. Both systems are intended to be used with a conventional extracorporeal transducer. The type of transducers specified for use with the UltraVision 2 system are both linear which is also used with the predicate system. A comparison of the transducers is provided in Table 2:

	HL5-10EPN	**L14-4**	**14L5**
Type	Linear	Linear	Linear
Frequency Bandwidth	5 – 12 MHz	5-15 MHz	5 – 14 MHz
Applications	• Breast • Testes • Thyroid • Musculoskeletal • Peripheral Vessel • Abdominal	• Breast • Testes • Thyroid • Musculoskeletal • Peripheral Vessel • Abdominal	• Breast • Testes • Thyroid • Musculoskeletal • Peripheral Vessel • Abdominal
Number of Elements	128	256	128
Modes of Operation	B, E, M, CFD,PWD	B, E, M, CFD, PWD	B, C, D, M
Array Footprint	38.1 mm	52 mm	39 mm
Acoustic output display standard	Track 1	Track 1	Track 3
Mechanical Index (MI)	.164	.82	1.1
I_{SPTA} (mW/cm^2)	83	75	114
Maximum Power (mW)	.35	15.3	27
P_r (MPa)	.45	2.142	4.26
Frequency (MHz)	7.64	7.55	6

Table 2. Probe Comparison

Operating Principle and Design:

Both the UltraVision 2 and the predicate system transmit ultrasonic energy into patients then perform post-processing of received echoes to generate on-screen displays of anatomic structures of the human body. Both systems are designed with an LCD display screen and hand-held transducers. Both systems support the same operating modes (B, CFD, M, E, Shear, PWD) and the same measurement functions for anatomic structures. The operation characteristics (installation and use, mode of operation) and the power supply are the same in both systems.

Non-clinical Test and Safety:

Clinical Test: Clinical testing not required

Non-clinical Test:

Testing according to the following safety standards are conducted on the subject device:

1. AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2 EMC Requirements for Medical Equipment
3. IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
4. Acoustic output testing as per the FDA guidance "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", dated September 9, 2008
5. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity, ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity

The UltraVision 2 system is in conformance with the standards described above which are the same or equivalent to those of the predicate device.

Biocompatibility:

The patient contact materials of human body surface are evaluated under ISO 10993 and determined acceptable for the specified usage of the system. Both systems have the same acceptance level for biocompatibility.

Conclusion:

Clinical studies are not required to support substantial equivalence for these conventional ultrasound systems. In addition, as discussed in the above technological comparison, the technological characteristics of the UltraVision 2 system are substantially equivalent to the referenced predicate device that has been previously cleared for USA distribution.

Substantially Equivalent Determination:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same operational characteristics as the previously cleared predicate device, or the device has the same intended use and different operational characteristics in which substantial equivalency can be

demonstrated in the device in comparison to the predicate device. In addition, the new device does not raise new questions regarding its safety and effectiveness as compared to the predicate device.

It is shown in this 510(k) submission that the difference between the UltraVision 2 and the predicate device does not raise any questions regarding its safety and effectiveness. The UltraVision 2, as designed and produced, is determined to be substantially equivalent to the predicate device.