Sedecal SA
% Ms. Laura Green
Consultant
Laura Green, LLC.
227 East 284th Street
WILLOWICK OH 44095

August 2, 2019

Re: K191813
Trade/Device Name: MobileDiagnost wDR 2.2
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: July 3, 2019
Received: July 5, 2019

Dear Ms. Green:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191813

Device Name

MobileDiagnost wDR 2.2

Indications for Use *(Describe)*

Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not for mammography.

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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6. 510(k) Summary K191813

SPECIAL 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	**July 3, 2019**	
Manufacturer:	SEDECAL SA C/ Pelaya, 9 – 13 Pol. Ind. Río de Janeiro 28110 Algete, Madrid Spain (España) Establishment registration number: 9617251	
Contact Person:	Laura Green of Laura Green, LLC 227 East 284th Street Willowick, Ohio 44095 Tel.: (404) 897-5675 Email: laurag9@roadrunner.com	
Device Name:	***MobileDiagnost wDR 2.2***	
Classification:	Classification Name	Mobile X-Ray System
	Classification Regulation:	21CFR 892.1720
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Primary product code:	IZL
	Secondary code:	MQB
Predicate Device:	Trade Name:	MobileDiagnost wDR 2.0
	Manufacturer:	Sedecal SA
	510(k) Clearance:	K141895-September 18, 2014
	Classification Regulation:	21CFR 892.1720
	Classification Name:	Mobile X-Ray System
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Product Code	IZL, MQB

Reference Device 1:	Trade Name:	Philips Eleva Workspot with SkyPlate Detectors
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K141736- July 25, 2014
	Classification Regulation:	21CFR 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Product Code	MQB, LLZ
Reference Device 2:	Trade Name:	Philips Eleva Workspot with SkyFlow
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K153318- December 22, 2015
	Classification Regulation:	21 CFR 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Product Code	MQB, LLZ
Reference Device 3:	Trade Name:	DigitalDiagnost C90
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K182973- January 11, 2019
	Classification Regulation:	21CFR 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Product Code	MQB, KPR, LLZ

Device description:

The ***MobileDiagnost wDR 2.2*** is a motorized mobile radiographic system consisting of a mobile base unit, a user interface consisting of

	Eleva Workspot combined with flat solid state X-ray detectors used to operate, generate, process and handle digital X- ray images. The ***MobileDiagnost wDR 2.2*** integrates a new wireless portable detector (SkyPlate E). The family of SkyPlate detectors (Large and Small) have already been integrated into the MobileDiagnost wDR 2.0 based on the K141736 pre-market submission.
Indications for use:	The Indication for Use of the ***MobileDiagnost wDR 2.2*** is identical to that of the currently marketed and predicate device, MobileDiagnost wDR 2.0 (K141895- September 18, 2014) and is as follows: *Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not for mammography.*
Fundamental scientific technology:	The fundamental scientific technology utilized in the ***MobileDiagnost wDR 2.2*** and the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895) is equivalent to high voltage generator, X-ray tube and Collimator. The ***MobileDiagnost wDR 2.2*** is provided with the Wireless portable detectors, Workstation for images post-processing, storage and viewing and image post processing algorithms that are the same as provided in the following Reference Devices that are manufactured by Philips Medical Systems. • Philips Eleva Workspot with SkyPlate Detectors (K141736, July 25, 2014) ,

- Philips Eleva Workspot with SkyFlow – (K153318, December 22, 2015),
- Philips DigitalDiagnost C90 - Image Post Processing algorithms - UNIQUE 2 (K182973, January 11, 2019)

A comparison of the technological characteristics of the ***MobileDiagnost wDR 2.2*** to the currently marketed and predicate MobileDiagnost wDR 2.0 is provided below in Table 1.

Modifications to the ***MobileDiagnost wDR 2.2*** include:

- Introduction of SkyPlate E detector and Grids
- Upgrade to UNIQUE 2 Post Processing software (previously cleared under K182973)
- Exposure @ zero degree column position to accommodate imaging in narrow rooms
- Exposure during Charging to offer use of the device while charging the battery
- Handles have been added to the Collimator for additional positioning functionality
- Keyless user access replaces the physical key previously required

The aforementioned modifications have been evaluated in safety risk assessment report. The risks associated with these changes are considered in the risk management report and risk management activities show that all risks are sufficiently mitigated and that the overall residual risks are acceptable.

Note: The outcome of this comparison demonstrates that the minor differences in the technological characteristics between the ***MobileDiagnost wDR 2.2*** and the currently

marketed and predicate MobileDiagnost wDR 2.0 (K141895- September 18, 2014) do not raise any new questions regarding safety or effectiveness.

Table-1 ***Comparison of technological characteristics of currently marketed and predicate MobileDiagnost wDR 2.0 versus the MobileDiagnost wDR 2.2***			
	Predicate Device: MobileDiagnost wDR2.0 (K141895)	***MobileDiagnost wDR2.2 (Pending)***	***Discussion & Conclusion***
Basic Information			
Base Unit Type	Mobile X-ray unit with wireless detector	Same	Identical; thus, demonstrating SE.
Dimensions: (l x w x h) In operation max.	2550 mm x 670 mm x 2125 mm	2577 mm x 670 mm x 2125 mm	The differences in the dimensions do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Dimensions: (l x w x h) In transport	1375 mm x 670 mm x1980 mm	1382 mm x 670 mm x 1960 mm	The differences in the dimensions do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
Dimensions: Source - floor distance	550 mm to 2020 mm	530 mm to 2020 mm	The differences in the dimensions do not impact the safety or effectiveness of the device. Thus, demonstrating SE.
X ray Tube assembly rotation around telescope arm axis	+/-180°	Same	Identical; thus, demonstrating SE.
X ray tube assembly around longitudinal tube axis	+90° to -30°	Same	Identical; thus; demonstrating SE.
Mains Supply	100 VAC/110 VAC/230 VAC±10% 50 Hz/60 Hz	Same	Identical; thus, demonstrating SE.
Mode of Releasing Exposure	Releasing Exposure via Hand switch or via Remote Control (Optional)	Same	Identical; thus, demonstrating SE.

Available Exposure Methods	Free exposure technique on film cassettes or CR systems and wireless portable detectors	Same	Identical; thus, demonstrating SE.
Detector			
Type	Digital wireless flat detector	Same	Identical; thus, demonstrating SE.
Detector Models	• SkyPlate Large (Trixell 3543EZ) • Skyplate Small (Trixell 2430EZ)	• SkyPlate Large (Trixell 3543EZ) • Skyplate Small (Trixell 2430EZ) • SkyPlate E large (Trixell 3543DR)	Addition of SkyPlate E detector does not impact the safety or effectiveness of the device. Thus, demonstrating SE
X-Ray Absorber	CsI Scintillator	Same	Identical; thus, demonstrating SE
Installation type	Portable	Same	Identical; thus, demonstrating SE
Readout Mechanism	Thin Film Transistor	Same	Identical; thus, demonstrating SE
Detector Size	Large: 384 x 460 x 16 mm Small: 328 x 268 x 16 mm	Large: 384 x 460 x 16 mm Small: 328 x 268 x 16 mm SkyPlate E Large: 384.5 x 460.5 x 16 mm	Identical; thus, demonstrating SE
Maximum X-ray Dose for Linear Response	50 µGy	Same	Identical; thus, demonstrating SE
Maximum Usable Dose	75 µGy	Same	Identical; thus, demonstrating SE
Image Processing	Eleva Workstation	Same	Identical; thus, demonstrating SE
Maximum Lifetime Dose	100 µGy	Same	Identical; thus, demonstrating SE
Detector Weight	Max 3 kg including .battery	Max 3.1 kg including battery	This difference in the Detector weight has no impact on clinical workflow. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
Image Size (X-ray field)	344.8 mm x 421.2 mm	345.0 mm x 426.0 mm	This difference in the Image Size (X-ray field) does not impact clinical Image Quality. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
Pixel Size	148 µm	160 µm	The difference of 12 µm pixel size does not impact the image resolution to an

			extent that can impact the clinical image quality. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
Image matrix size (Number of pixels)	2330 x 2846 pixels	2156 x 2662 pixels	Infinitesimal change in the image size (X-ray field) and reduction in number of pixels due to 160 µm pixel size does not impact clinical Image Quality. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
Nyquist Frequency	3.38 lp/mm	3.125 lp/mm	This difference in the Nyquist Frequency does not impact clinical Image Quality. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
Modulation Transfer Function (MTF), typical values	1 lp/mm 61% 2 lp/mm 30% 3 lp/mm 14% 3.38 lp/mm 10% (Nyquist)	1 lp/mm 62% 2 lp/mm 34% 3 lp/mm 18% 3.125 lp/mm 16% (Nyquist)	This difference in the Modulation Transfer Function does not impact clinical Image Quality. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
Detective Quantum Efficiency (DQE), typical values	DQE at 2.0 µGy Lp/mm % 0.05 70 1 51 2 42 3 29 3.38 19 (Nyquist)	DQE at 2.0 µGy Lp/mm % 0.05 70 1 51 2 42 3 22 3.125 18 (Nyquist)	This difference in the Detective Quantum Efficiency does not impact clinical Image Quality. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
ADC Digitisation	16 Bit	16 Bit	Identical.; thus, demonstrating SE;
Signal to Electronic Noise Ratio (SENR)	Min 38 dB – typical: 43 dB (@ 1 µGy)	Min 37 dB – typical: 42.8 dB (@ 1 µGy)	Identical; thus, demonstrating SE
Data Interface to Workstation	• AP to workspot: 1 GBit/s Ethernet • Detector Ethernet via BUC: 100 Mbit/s Ethernet	Same	Identical; thus, demonstrating SE

	• Detector to AP: 150 Mbit/s WLAN (gross transfer rate)		
Grids			
Type	• Large Grids for SkyPlate Large (468 mm × 476 mm × 25 mm) • Small Grid for SkyPlate Small (280 mm × 354 mm × 25 mm)	• Large Grids for SkyPlate Large (468 mm × 476 mm × 25 mm) • Small Grid for SkyPlate Small (280 mm × 354 mm × 25 mm) • Large Grids for SkyPlate E (468 mm × 476 mm × 23 mm)	Addition of new grids for Skyplate E introduction has no impact on clinical workflow. Therefore, no impact on safety or effectiveness of the device; thus, demonstrating SE
Design characteristics			
X – Ray Tube			
Tube	E7886X used with 40kW Generator E7865X used with 20kW Generator	Same	Identical.; thus, demonstrating SE
Material	Rhenium-Tungsten, Molybdenum	Same	Identical; thus, demonstrating SE.
Maximum tube voltage	150 kVp	Same	Identical; thus, demonstrating SE.
Nominal focal spot	E7886X 0.7/1.3 E7865X- 0.3/1.0	Same	Identical; thus, demonstrating SE.
Anode type	Rotating	Same	Identical; thus, demonstrating SE.
Nominal anode input power	20kW, 40kW	Same	Identical; thus, demonstrating SE.
Generators			
Power Configurations	20kW and 40kW	Same	Identical.; thus, demonstrating SE
Column Configuration	Standard Column Short Column (Optional)	Standard Column Sliding Column	Sliding Column provides better viewing while driving the system. Introduction of Sliding column does not impact the safety or effectiveness of the device; thus, demonstrating SE
System Power ON/OFF	Using Physical Key	Keyless user access	Keyless user access provides authenticated access to System Power ON. Introduction of Keypad does not impact the safety or effectiveness of the

			device; thus, demonstrating SE
Exposure @ zero degree column position	No Exposure allowed when the column is at 0 Degree	Exposures are allowed when the column is at 0 Degree	Exposure @ 0 degree column position allows the user to perform examinations in space constraints situations. This difference however does not impact the safety or effectiveness of the device; thus, demonstrating SE
Exposure during Charging	Exposures are not allowed when the unit is connected to mains (Note: exposure energy is drawn from generator batteries and not from mains)	Exposures are allowed when the unit is connected to mains (Note: exposure energy is drawn from generator batteries and not from mains)	Exposure during charging allows the user to charge the system even during exam preparation. Since, exposure energy is still drawn from generator batteries and not from mains therefore this change does not impact the safety or effectiveness of the device; thus, demonstrating SE
Collimator			
Operation mode	Manual with light field indicator, multilayer, squared field	Same	Identical; thus, demonstrating SE.
Shape of the beam	Rectangular	Same	Identical; thus, demonstrating SE.
Handles on Collimator	Handles are available only to move the Tube head.	Handles can be used to move both Tube head and Collimator	Handles on Collimator provides ease of use to the user. This difference however does not impact the safety or effectiveness of the device; thus, demonstrating SE
External Connectivity			
DICOM	DICOM compatible	Same	Identical; thus, demonstrating SE.
Software Platform			
Software	Eleva WorkSpot with SkyFlow	Same	The *MobileDiagnost wDR 2.2* and the currently marketed predicate MobileDiagnost wDR 2.0 both use the same software platform, the Philips Eleva Workspot with SkyFlow (K153318). Therefore, there is no impact on the safety and effectiveness of the device;

			thus, demonstrating SE.
Image Processing Algorithm	UNIQUE	UNIQUE 2	UNIQUE 2 provides improved image processing, reduced noise and improved contrast. Further, UNIQUE 2 is already cleared under K182973 (January 11, 2019) Upgrading to UNIQUE2 does not alter the clinical workflow, hence no impact on the safety or effectiveness of the device; thus, demonstrating SE

Based on the information provided above, the ***MobileDiagnost wDR 2.2*** is considered substantially equivalent to the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895-September 18, 2014) with regards to fundamental scientific technology.

Summary of Non-Clinical Performance data:

This 510(k) premarket notification contains the technical documentation, which demonstrates that the ***MobileDiagnost wDR 2.2*** is substantially equivalent to the currently marketed and predicate *MobileDiagnost wDR 2.0 (K141895-September 18, 2014).* The technical documentation includes non-clinical verification / validation tests. These tests were performed on the ***MobileDiagnost wDR 2.2*** according to the following international and FDA-recognized consensus standards:

- IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (Edition 3.1). FDA/CDRH recognition number 19-4.
- IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbances – Requirements and tests (Edition 4.0 2014). FDA/CDRH recognition number 19-8.

- IEC 60601-1-3, Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance-Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment. (Edition 2.1 2013). FDA/CDRH recognition number 12-269.
- IEC 60601-1-6, Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability (Edition 3.1 2013). FDA/CDRH recognition number 5-89.
- IEC 60601-2-54, Medical Electrical Equipment-Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy (Edition 1.1 2015). FDA/CDRH recognition number 12-296.
- IEC 62304 Medical device software - Software life cycle processes (Edition 1.0;2006) FDA/CDRH recognition number 13-32
- IEC 62366 IEC Application of Usability Engineering to Medical Devices (Edition 1.0 2015). FDA/CDRH recognition number 5-114.
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2007). FDA/CDRH recognition number 5-40.
- ISO 10993-1 Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process (Edition 4.0 2009). FDA/CDRH recognition number 2-220
- IEC60601-2-28 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis, (Edition 2.0 2010-03). FDA/CDRH recognition number 12-204
- IEC 62220-1 Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging (Edition 1.0 2015-03) FDA/CDRH recognition number 12-289
- NEMA PS 3.1 - 3.20 Digital Imaging And Communications In Medicine (DICOM) Set

- Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices, issued September 1, 2016
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005
- Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 28, 2017

Non-clinical verification and validation tests have been performed with regards to the intended use, the technical claims, requirement specifications, and the risk management results.

Non-clinical verification and validation test results demonstrate that the ***MobileDiagnost wDR 2.2****:*

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents.
- meets the acceptance criteria and is adequate for its intended use.

Therefore, the ***MobileDiagnost wDR 2.2*** is substantially equivalent to the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895-September 18, 2014)

Summary of Clinical Data:

The ***MobileDiagnost wDR 2.2*** does not require clinical study since substantial equivalence to the primary currently marketed and predicate device *MobileDiagnost wDR 2.0 (K141895- September 18, 2014)* was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

Furthermore, the SkyPlate E detector also has the same design, technology and Image acquisition workflow compared to the previously cleared detector (SkyPlate

	Family detectors, K141736- July 25, 2014), used in the marketed predicate device *MobileDiagnost wDR 2.0 (K141895- September 18, 2014)*, except difference in the pixel size. All technical detector characteristics that potentially have an influence on image quality are assessed and verified according to FDA Guidance for Industry and Food and Drug Administration Staff: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices; issued on September 1, 2016. Non-clinical information is sufficient to support the substantial equivalence as per chapter VII- Non clinical Considerations of FDA Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.
Substantial Equivalence Conclusion:	The ***MobileDiagnost wDR 2.2*** is substantially equivalent to the currently marketed and predicate MobileDiagnost wDR 2.0 (K141895, September 18, 2014) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, ISO 14971, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-54, IEC 60601-1-6, IEC 60601-2-28, IEC 62304, IEC 62366, and ISO 10993-1. The results of these tests demonstrate that the ***MobileDiagnost wDR 2.2*** met the acceptance criteria and is adequate for its intended use.