MedNovel Technology Ltd.
℅ Jia Yu
Quality and Regulatory Affairs Manager
1154 Cadillac Court
MILPITAS CA 95035

October 9, 2019

Re: K190314
Trade/Device Name: Advanced Intelligent Volumetric Ultrasound System, Model AiVUS 1000
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, LLZ, ITX
Dated: September 9, 2019
Received: September 12, 2019

Dear Jia Yu:

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

4. Indications for Use Statement

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)*

K190314

Device Name

Advanced Intelligent Volumetric Ultrasound System, Model AiVUS 1000

Indications for Use *(Describe)*

The MedNovel Model AiVUS 1000 is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of patient's breast when used with an automatic scanning linear array probe. The device is not intended to be used as a replacement for mammography.

It is an adjunct (add on) accessory for existing ultrasound imaging systems and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest.

The MedNovel Model AiVUS 1000 system is capable of visually reconstructing the ultrasonic images for review with DICOM type files which will assist the doctor in making diagnoses of any abnormalities detected.

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

[X] 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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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

5. 510(k) Summary

510(k) Summary **K190314**

Date Prepared:	May.20, 2019	
Manufacturer:	MedNovel Technology Ltd	
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Device Name	Advanced Intelligent Volumetric Ultrasound System, Model AiVUS 1000	
Classification	Classification name:	Ultrasonic Pulsed Echo Imaging System
	Classification Regulation:	21 CFR 892.1560 Ultrasonic pulsed echo imaging system 21 CFR 892.2050 Picture archiving and communications system 21 CFR 892.1570 Diagnostic ultrasonic transducer
	Classification Panel:	Radiology
	Device Class:	II
	Primary Product Code:	IYO, LLZ, ITX
Primary Predicate Device	Trade name:	Acuson S2000 ABVS Ultrasound System
	Manufacturer:	Siemens Medical Solutions USA, Inc.
	510(k) Clearance:	K081148
	Classification Regulation:	21 CFR 892.1560
	Classification name:	Ultrasonic Pulsed Echo Imaging System
	Classification Panel:	Radiology
	Device class	II
	Product Code:	IYN, IYO, ITX
Reference Device #1	Trade name:	Breast Volume Navigator
	Manufacturer:	MetriTrack, LLC
	510(k) Clearance:	K141870
	Classification Regulation:	21 CFR 892.1560
	Classification name:	Ultrasonic Pulsed Echo Imaging System
	Classification Panel:	Radiology
	Device class	II

	Product Code:	IYO
Reference Device #2	Trade name:	TomTec Echo-Scan
	Manufacturer:	TomTec Imaging Systems, Inc.
	510(k) Clearance:	K963807
	Classification Regulation:	21 CFR 892.1560
	Classification name:	Ultrasonic Pulsed Echo Imaging System
	Classification Panel:	Radiology
	Device class	II
	Product Code:	IYO
Device Description	The Model AiVUS 1000 is a transducer guiding adjunct which is intended to work in combination with specified legally marketed Ultrasound Diagnostic System (MyLab Gamma, K161359) and Transducer (SL1543, K132231) and previously released exam tables. The Model AiVUS 1000 system is comprised of a patient scanning system and display system. The Model AiVUS 1000 performs an automatic scan of the breast(s) using a probe guiding mechanism(s) imbedded within the scan module. The imbedded system software plots the path of the automated scan, records the ultrasonic images from paired ultrasound system, and has the capability to both display the real-time B-mode ultrasonic images acquired and after the fact review of the breast exam in DICOM supported file format as a means of providing adjunctive information after a patient obtains a mammogram. This adjunctive information may be useful to physicians wishing to have additional information to make diagnoses of any abnormalities detected. The patient scanning system consists of a scan module and associated assembly and electronics. The scan module is centered above a patient's breast and then performs scanning by using the ultrasound linear transducer arrays. While scanning, the real-time images are acquired by video frame grabber. Acquired images are then reconstructed by the Model AiVUS 1000 system software to display the breast images on the Model AiVUS 1000 display system. The Model AiVUS 1000 display system has two adjustable touch panels and associated assembly and electronics.	
Intended Use/ Indication for use	The MedNovel Model AiVUS 1000 is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of patient's breast when used with an automatic scanning linear array probe. The device is not intended to be used as a replacement for mammography. It is an adjunct (add on) accessory for existing ultrasound imaging systems and is intended to control position and movement of ultrasound	

	transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. The MedNovel Model AiVUS 1000 system is capable of visually reconstructing the ultrasonic images for review with DICOM type files which will assist the doctor in making diagnoses of any abnormalities detected.
Technology & Fundamental Scientific Technology	The Model AiVUS 1000 system works together with legally approved ultrasound imaging systems (LAUIS). The Model AiVUS 1000 system acquires real-time B-mode ultrasonic images by video connection from the LAUIS. While scanning, the Model AiVUS 1000 system moves the transducer along the planned path inside the region of interest specified by the operator. After the scanning, the acquired images are reconstructed and stored as a multi-frame DICOM file. The AiVUS 1000 system is intended for acquiring ultrasound images only. Tools for evaluating abnormalities identified (size, location, etc.) are contained in the workstation software which is a standalone product and will be submitted for clearance later.
Determination of Substantial Equivalence	MedNovel Tech claims that the Model AiVUS 1000 system is substantially equivalent to the predicate devices (K081148 – Acuson S2000 ABVS Ultrasound System, K141870 – Breast Volume Navigator and K963807 – TomTec Echo-Scan). MedNovel Tech claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical and operational specifications compared to the predicate devices. This comparison of the specifications demonstrates the functional equivalence of the products. The difference discussed in the above chapters includes: (Details please see Section 12) • working mechanism • structure • electric and environment requirements • connectivity • connection to ultrasound system The safety concerns about structure, main power, connectivity and connection to ultrasound system could be addressed by TUV report. As to working mechanism, safety concerns come from image distortion, which has been addressed in the Risk Management File (39, 40, 42, 43, 44, 45) for the device. In all, the differences discussed in this section do not raise new issues of safety and effectiveness. Verification testing demonstrated that no adverse effects have been introduced by these differences. Therefore, MedNovel believes that the Model AiVUS 1000 is as safe and

	effective and performs in a substantially equivalent manner to the predicate device(s).
Summary of Non-Clinical Tests	The Model AiVUS 1000 systems has been evaluated for biocompatibility, as well as electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The Model AiVUS 1000 systems complies with voluntary standards and FDA Guidance documents: 1. AAMI/ANSI ES60601-1, Medical Electrical Equipment –Medical electrical equipment- Part1: General requirements for basic safety and essential performance 2. IEC60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests 3. IEC60601-1-6, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability 4. IEC62366-1, Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices 5. ISO10993-1, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process 6. ISO10993-5，Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity 7. ISO10993-10，Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization 8. ANSI AAMI IEC62304, Medical Device Software - Software Life Cycle Processes 9. ISO14971, Medical device - Application of risk management to medical devices 10. ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1:General requirements 11. Guidance for Industry and FDA Staff — Content of Premarket Submissions for Management of Cyber security in Medical Devices (issued October 2, 2014) 12. Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1,"Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (issued June 16, 2016)

	13. Guidance for Industry and FDA Staff-Information to Support a Claim of Electromagnetic Compatibility(EMC) of Electrically – Powered Medical Devices (issued July 11,2016) 14. Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Guidance for Industry and FDA Staff Performance Testing: Verification testing was performed in Image Simulation Tests on breast phantoms. All items in the test plan were verified and passed. Clinical sample images in appendix H were provided to support the ability of proposed Model AiVUS 1000 to generate diagnostic quality images that are at least as good as those of the current standard of care, handheld ultrasound examination. Additionally, verification/validation tests results metrics DOC0000101 Rev A have been performed to address intended use, the technical claims, requirement specifications and the risk management results. The results demonstrate that the Model AiVUS 1000: • Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents. • Meet the accept criteria and is adequate for its intended use. The results of these performance tests indicate that the Model AiVUS 1000 is substantially equivalent to the listed predicate devices (Acuson S2000 ABVS Ultrasound System (K081148), Breast Volume Navigator(K141870), TomTec ECHO-SCAN(K963807).
Summary of Clinical Tests	The proposed Model AiVUS 1000 system did not require formal clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing. However, clinical sample images are used as an output to confirm that the indication for use for the device is met. In the performance of these tests the Model AiVUS 1000 system met the defined criteria for success. In addition, since different size of breast types (A, B, C, D cup size) and different subject ethnicities (Han, Caucasoid, African) with a variety of lesions were captured during the collection of the clinical sample image data, all the indication for use are evidenced. The proposed indication for use is satisfied.
Conclusion	In summary, these data support the claim that the design, intended use, technology and principal technological components of the proposed Model AiVUS 1000 are substantially equivalent to the currently marketed primary predicate device ABVS (K081148) and two referenced devices (K141870 and K963807). Based on the information provided above, the proposed

	Model AiVUS 1000 does not raise different questions of safety and effectiveness compare to the currently marketed primary predicate device ABVS(K081148). The proposed Model AiVUS 1000 is identical to the primary predicate device ABVS(K081148), and therefore is considered substantially equivalent. 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. The results of these tests demonstrate that the proposed Model AiVUS 1000 meets the acceptance criteria and is adequate for its intended use.