DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 5, 2017

Linkquest Inc.
C/0 Dr. Xiaolong Yu
President
6749 Top Gun Street
#100
San Diego CA 92121

Re: K172059
Trade/Device Name: LinkQuest Diagnostic Ultrasound System model SQ860
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 28, 2017
Received: July 7, 2017

Dear Dr. 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. 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,

For

Robert Ochs
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k172059

Device Name
LinkQuest Diagnostic Ultrasound System model SQ860

Indications for Use *(Describe)*
The LinkQuest Diagnostic Ultrasound System model SQ860 is intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients and neonates. It is intended for use by or on the order of a physician or similarly qualified health care professional in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Indications for Use Form

System: **SQ 860 Diagnostic Ultrasound Systems**
Transducer: **N/A**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Fetal	N	N	N		N	N(*1)	N(*2)
Abdominal	N	N	N	N	N	N(*1)	N(*2)
Small Organ (Specify)	N	N	N		N	N(*1)	N(*2)
Neonatal Cephalic	N	N	N		N	N(*1)	N(*2)`
Adult Cephalic	N	N	N		N	N(*1)	N(*2)
Pediatric	N	N	N	N	N	N(*1)	N(*2)
Trans-rectal	N	N	N		N	N(*1)	N(*2)
Trans-vaginal	N	N	N		N	N(*1)	N(*2)
Cardiac	N	N	N	N	N	N(*1)	N(*2)
Peripheral Vessel	N	N	N		N	N(*1)	N(*2)
MSK Conventional	N	N	N		N	N(*1)	N(*2)
MSK Superficial	N	N	N		N	N(*1)	N(*2)
Vascular Access	N	N	N		N	N(*1)	N(*2,*4)
Nerve Block	N	N	N		N	N(*1)	N(*2,*3)
Other (Specify)							

N = New indication; P = Previously cleared
Additional Comments:
Small Organ: Breast, Thyroid, Testicle
*1. B/M, B/PWD, B/CWD, B/CF/PWD, (B includes Simple B (SB) imaging, Harmonic Imaging (HI) , SB/HI)
*2. Elastography, Power Doppler (DPD). Biopsy Guidance Imaging, Panoramic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live *3D/4D* Imaging.
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

System: **SQ 860 Diagnostic Ultrasound Systems**
Transducer: **A8L1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Fetal	N	N	N		N	N(*1)	N(*2)
Abdominal	N	N	N		N	N(*1)	N(*2)
Small Organ (Specify)	N	N	N		N	N(*1)	N(*2)
Neonatal Cephalic	N	N	N		N	N(*1)	N(*2)`
Adult Cephalic	N	N	N		N	N(*1)	N(*2)
Pediatric	N	N	N		N	N(*1)	N(*2)
Trans-rectal							
Trans-vaginal							
Cardiac							
Peripheral Vessel	N	N	N		N	N(*1)	N(*2)
MSK Conventional	N	N	N		N	N(*1)	N(*2)
MSK Superficial	N	N	N		N	N(*1)	N(*2)
Vascular Access	N	N	N		N	N(*1)	N(*2,*4)
Nerve Block	N	N	N		N	N(*1)	N(*2,*3)
Other (Specify)							

N = New indication; P = Previously cleared
Additional Comments:
Small Organ: Breast, Thyroid, Testicle
*1. B/M, B/PWD, B/CWD, B/CF/PWD, (B includes Simple B (SB) imaging, Harmonic Imaging (HI) , SB/HI)
*2. Elastography, Power Doppler (DPD). Biopsy Guidance Imaging, Panoramic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live *3D/4D* Imaging.
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

System: **SQ 860 Diagnostic Ultrasound Systems**
Transducer: **A3C1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Fetal	N	N	N		N	N(*1)	N(*2)
Abdominal	N	N	N		N	N(*1)	N(*2)
Small Organ (Specify)	N	N	N		N	N(*1)	N(*2)
Neonatal Cephalic							
Adult Cephalic							
Pediatric	N	N	N		N	N(*1)	N(*2)
Trans-rectal							
Trans-vaginal							
Cardiac							
Peripheral Vessel	N	N	N		N	N(*1)	N(*2)
MSK Conventional	N	N	N		N	N(*1)	N(*2)
MSK Superficial	N	N	N		N	N(*1)	N(*2)
Vascular Access							
Nerve Block							
Other (Specify)							

N = New indication; P = Previously cleared
Additional Comments:
Small Organ: Breast, Thyroid, Testicle
*1. B/M, B/PWD, B/CWD, B/CF/PWD, (B includes Simple B (SB) imaging, Harmonic Imaging (HI) , SB/HI)
*2. Elastography, Power Doppler (DPD). Biopsy Guidance Imaging, Panoramic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live *3D/4D* Imaging.
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

System: **SQ 860 Diagnostic Ultrasound Systems**
Transducer: **A3S1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Fetal							
Abdominal	N	N	N	N	N	N(*1)	N(*2)
Small Organ (Specify)							
Neonatal Cephalic	N	N	N		N	N(*1)	N(*2)`
Adult Cephalic	N	N	N		N	N(*1)	N(*2)
Pediatric	N	N	N	N	N	N(*1)	N(*2)
Trans-rectal							
Trans-vaginal							
Cardiac	N	N	N	N	N	N(*1)	N(*2)
Peripheral Vessel							
MSK Conventional							
MSK Superficial							
Vascular Access							
Nerve Block							
Other (Specify)							

N = New indication; P = Previously cleared
Additional Comments:
Small Organ: Breast, Thyroid, Testicle
*1. B/M, B/PWD, B/CWD, B/CF/PWD, (B includes Simple B (SB) imaging, Harmonic Imaging (HI) , SB/HI)
*2. Elastography, Power Doppler (DPD). Biopsy Guidance Imaging, Panoramic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live *3D/4D* Imaging.
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

System: **SQ 860 Diagnostic Ultrasound Systems**
Transducer: **E8C1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Fetal							
Abdominal							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Pediatric							
Trans-rectal	N	N	N		N	N(*1)	N(*2)
Trans-vaginal	N	N	N		N	N(*1)	N(*2)
Cardiac Adult							
Peripheral Vessel							
MSK Conventional							
MSK Superficial							
Vascular Access							
Nerve Block							
Other (Specify)							

N = New indication; P = Previously cleared
Additional Comments:
Small Organ: Breast, Thyroid, Testicle
*1. B/M, B/PWD, B/CWD, B/CF/PWD, (B includes Simple B (SB) imaging, Harmonic Imaging (HI) , SB/HI)
*2. Elastography, Power Doppler (DPD). Biopsy Guidance Imaging, Panoramic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live *3D/4D* Imaging.
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

System: **SQ 860 Diagnostic Ultrasound Systems**
Transducer: **A3D1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Fetal	N	N	N		N	N(*1)	N(*2)
Abdominal	N	N	N		N	N(*1)	N(*2)
Small Organ (Specify)	N	N	N		N	N(*1)	N(*2)
Neonatal Cephalic							
Adult Cephalic							
Pediatric	N	N	N		N	N(*1)	N(*2)
Trans-rectal							
Trans-vaginal							
Cardiac Adult							
Peripheral Vessel	N	N	N		N	N(*1)	N(*2)
MSK Conventional							
MSK Superficial							
Vascular Access							
Nerve Block							
Other (Specify)							

N = New indication; P = Previously cleared
Additional Comments:
Small Organ: Breast, Thyroid, Testicle
*1. B/M, B/PWD, B/CWD, B/CF/PWD, (B includes Simple B (SB) imaging, Harmonic Imaging (HI) , SB/HI)
*2. Elastography, Power Doppler (DPD). Biopsy Guidance Imaging, Panoramic Imaging, Tissue Doppler Imaging, Compound Imaging, Freehand 3D Imaging, Live *3D/4D* Imaging.
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

510K SUMMARY

LinkQuest Diagnostic Ultrasound System and Transducers Model SQ860

Submitter: LinkQuest, Inc.
6749 Top Gun Street, Suite 100
San Diego, CA 92121
Phone: (858) 623-9900
Fax: (858) 623-9918

Contact Person: Xiaolong Yu, Ph.D.
Phone: (858) 623-9900
Fax: (858) 623-9918
E-Mail: xyu@link-quest.com

Trade Name: LinkQuest Diagnostic Ultrasound System model SQ860

Classification and Regulatory Class:

Description	Class	Product Code
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System	II	IYN
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System	II	IYO
21 CFR 892.1570 Diagnostic Ultrasound Transducer	II	ITX

Panel Identification: Radiolagy

Prior Submissions Statement: No previous submissions for this device.

Device Description:
The LinkQuest Diagnostic Ultrasound System SQ860 is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color-Mode, PW-Mode, TDI mode, CW mode, 3D/4D mode, Elastography (Strain imaging) and/or the combined modes. This system is a **Track 3** device that employs a set of probes that include linear array, convex array, Intracavity array, phased array and 4D array with a frequency range of approximately 2 MHz to 10.0 MHz.

Predicate Devices:

Ultrasonics Touch k083095 Manufactured by: Ultrasonix Medical Corporation
130-4311 Viking Way
Richmond, British Columbia
Canada V6V 2K9

SonoSite maxx k130173 Manufactured by: FUJIFILM SonoSite Inc
21919 301 Drive SE
Bothell, WA 98021-3904

Indications for Use:
The LinkQuest Diagnostic Ultrasound System and Transducers model SQ860 are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients and neonates. They are intended for use by or on the order of a physician or similarly qualified health care professional in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

Clinical Test: Clinical testing is not required.

Non - clinical Test:
The following safety standards and regulations are complied with by the subject device:

1. IEC 60601-1:2005 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance;
2. IEC 60601-1-2:2007 for electromagnetic compatibility;
3. IEC 60601-1-2-37,
4. ISO 14971.
5. NEMA UD-2 2004: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
6. AIUM and NEMA UD-3 2004: The Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
7. ISO 10993 Biological Evaluation of Medical Devices

Comparison with predicate device
SQ860 Diagnostic Ultrasound System is comparable with and substantially equivalent to the listed predicate devices. SQ860 has the similar technological characteristics, is comparable in key safety and effectiveness features, and has the similar intended uses and basic operating modes as the predicate devices.

Substantially Equivalent Dtermination
The evaluation of the LinkQuest Diagnostic Ultrasound Systems and Transducers based on the technical characteristics and the results of the performance tests we conclude that SQ860 Diagnostic Ultrasound System and Transducers are substantially equivalent and as safe and effective as the predicate devices.