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

December 2, 2016

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

Re: K162972
Trade/Device Name: ExactVu High Resolution Micro-Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX, OIJ
Dated: November 29, 2016
Received: November 30, 2016

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,

For

Robert Ochs, Ph.D.
Acting 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)*
TBD

Device Name
ExactVu™ High Resolution Micro-Ultrasound System

Indications for Use *(Describe)*
The ExactVu High Resolution Micro-Ultrasound System is intended for use by qualified medical professionals for diagnostic ultrasound imaging or fluid flow analysis of the human body; the intended uses are:

Small Organ (prostate)
Transrectal

The system may be used with patients of all ages, but is not designed for pediatric or fetal use.

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.

Table 1.3.1: Diagnostic Ultrasound Indications for Use Form – ExactVu™ High Resolution Micro-Ultrasound System

System:	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer:	NA						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate) [1]	N						1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	N						1
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.) DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: Includes imaging to assist in the placement of needles for prostate biopsy procedures.

Table 1.3.2: Diagnostic Ultrasound Indications for Use Form – *EV29L™ High Resolution Transrectal Side-fire Transducer*

System:	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer:	EV29L						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)[1]	N						1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	N						1
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.) DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: Includes imaging to assist in the placement of needles for prostate biopsy procedures.

Table 1.3.3: Diagnostic Ultrasound Indications for Use Form – EV9C™ Transrectal End-fire Transducer

System:	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer:	EV9C						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate) [1]	N						1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	N						1
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.) DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: Includes imaging to assist in the placement of needles for prostate biopsy procedures.

Table 1.3.3: Diagnostic Ultrasound Indications for Use Form – Needle guide for use with EV29L™ High Resolution Transrectal Side-fire Transducer

System:	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer:	EV29L						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B (2D)	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate) [1]	N						1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	N						1
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.) DERMATOLOGY							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

1: Provides a mechanical means for performing needle / instrument guided procedures with the use of the diagnostic ultrasound transducer, EV29L

510(K) Summary

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.

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

Exact Imaging, Inc.
7676 Woodbine Avenue
Markham, ON L3R 2N2
Canada

Corresponding Official: Karina Torres
Manager, Regulatory Affairs and Quality Assurance

E-mail: ktorres@exactimaging.com
Telephone: (905) 415-0030
Facsimile: (905) 415-0031
Date prepared: September 1st, 2016

2) 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 with Accessories

Proprietary Name

ExactVu™ High Resolution Micro-Ultrasound System

Classification Names

Name	FR Number	Product Code
Ultrasonic pulsed echo imaging system	892.1560	IYO
Diagnostic Ultrasound Transducers	892.1570	ITX
Biopsy Needle Guide	892.1560	OIJ

Classification Panel

Radiology

EXACT IMAGING

3) Identification of the predicate or legally marketed device:

- Flex Focus 1202 Ultrasound Scanner (K081154) (Primary Predicate)
- FUJIFILM SonoSite Vevo MD Imaging system (K160674) (Reference Device)

4) Device Description:

The ExactVu high resolution micro-ultrasound system is intended for use by qualified medical professionals for diagnostic ultrasound imaging, data processing and guidance of puncture and biopsy. The ExactVu System is comprised of transducers responsible for ultrasound signal generation and recording, a needle guide and a main unit that controls the transducers, processes the acoustic data, and processes and displays images.

5) Intended Use:

The ExactVu High Resolution Micro-Ultrasound System is intended for use by qualified medical professionals for diagnostic ultrasound imaging or fluid flow analysis of the human body; the intended uses as defined by FDA guidance documents, is:

Small Organ (prostate)
Transrectal

The system may be used with patients of all ages, but is not designed for pediatric or fetal use.

6) Technological Characteristics:

The ExactVu High Resolution Micro-Ultrasound System ("ExactVu") that is the subject of this submission is substantially equivalent to the predicate devices. The same fundamental scientific technology and general ultrasound principles that are used for ExactVu are also used on the predicate devices indicated. Each of ExactVu and the indicated predicates are Track 3 devices.

Feature	ExactVu	Flex Focus 1202 (Primary Predicate)	Vevo MD (Reference Device)
Manufacturer	Exact Imaging Inc.	BK Medical	FUJIFILM SonoSite
Intended use (Clinical application)	Transrectal Small Parts (organs)	Abdominal Cardiac Fetal (incl. Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Musculo-skeletal	Abdominal Pediatric Small Organ (breast, thyroid, testicles, prostate) Musculo-skeletal (conventional) Musculo-skeletal (superficial) Peripheral vessel Dermatology

Modes of Operation	B-mode (2-D Grayscale Imaging, Transverse, CFM and combinations	B-mode (2-D Grayscale Imaging, M, PWD, CFM and combinations, Tissue Harmonic Imaging	B-mode (2D Grayscale Imaging) Color Doppler Combination Modes M-mode
MI Indication	Yes	Yes	Yes
TI Indication	Yes	Yes	Yes
Electrical Safety	TUV, IEC 60601-1	UL, IEC 60601-1	CSA IEC 60601-1
510(k) Track	Track 3	Track 3	Track 3
Center Frequency Range	3.5-29 MHz	1.8-18 MHz	15-49MHz
Transducer Types	Endocavity Linear Endocavity Curved Array	Endocavity Linear Endocavity Curved Array Endocavity Biplane Endocavity Triplane Linear Curved Array	Linear Array
#Transmit Channels	128 channels	Not available	64 digital channels
#Receive Channels	128 channels	Not available	64 digital channels
DICOM	Not supported	DICOM, Print, Modality Worklist, Storage Commitment, Modality Performed Procedure Steps (MPPS)	DICOM 3.0 Store Print Modality Worklist Perform Procedure Step (PPS) Storage Commitment NEMA PS3.15 2003

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The ExactVu System has been evaluated for electrical, thermal, mechanical and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated, and the device has been found to conform to applicable mandatory medical device safety standards. Assurance of quality was established by employing the following elements of product development: Design Phase Reviews, Risk Assessment, Requirements Development, System and Software Verification, Hardware Verification, Safety Compliance Verification, Clinical Evaluation. All patient contact materials are biocompatible and are materials that are already used in other legally marketed devices or meet 10993-1.

The ExactVu System is designed to comply with the following voluntary standards:

Reference No	Recognition No	Title
AAMI/ANSI/ISO 10993-1	2-156	ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
IEC 60601-1	19-4	AAMI / ANSI ES60601-1:2005/(R) 2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012. Medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod)
IEC 60601-1-2	19-1	IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
IEC 60601-2-37	9-91	IEC 60601-2-18: Edition 3.0 2009-08, Medical Electrical Equipment - Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment.
IEC 60601-2-37	12-209	IEC 60601-2-37:2007, Particular Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
NEMA UD 2-2004	12-105	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004	12-100	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine

Summary of Clinical Tests:

The ExactVu System, transducers and needle guide, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

8) Conclusion:

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The ExactVu device and predicate devices conform to applicable electromedical device safety standards with compliance verified through independent evaluation and meet FDA requirements for Track 3 devices, have biosafety equivalence and

are manufactured using the same ISO 13485 quality system. Exact Imaging, Inc. believes that the ExactVu system is substantially equivalent with regard to safety and effectiveness to the predicate devices.