April 30, 2018

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

Re: K180636
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: April 23, 2018
Received: April 24, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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 **K180636**

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 indications for use 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.

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

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

System	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer	N/A						
Intended Use	Diagnostic ultrasound imaging of the human body as follows:						
	Mode of Operation						
Clinical Application	**B (2D Mode)**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (specify)**	**Other (specify)**
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)	P, Note 2						P, Note 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal	P, Note 2						P, Note 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 ; E= added under this appendix

All items marked “P” were previously cleared by 510(k) number K162972.

Additional Comments:

1. Includes imaging to assist in the placement of needles for prostate biopsy procedures.
2. Includes an option to use MRI data with micro-ultrasound images to support MRI image-guided workflows.

Diagnostic Ultrasound Indications for Use Form – 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 of the human body as follows:						
	Mode of Operation						
Clinical Application	**B (2D Mode)**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (specify)**	**Other (specify)**
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)	P, Note 2						P, Note 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal	P, Note 2						P, Note 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 ; E= added under this appendix

All items marked "P" were previously cleared by 510(k) number K162972.

Additional Comments:

1. Includes imaging to assist in the placement of needles for prostate biopsy procedures.
2. Includes an option to use MRI data with micro-ultrasound images to support MRI image-guided workflows.

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 of the human body as follows:						
	Mode of Operation						
Clinical Application	**B (2D Mode)**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (specify)**	**Other (specify)**
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)	P						P, Note 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal	P						P, Note 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 ; E= added under this appendix

All items marked “P” were previously cleared by 510(k) number K162972.

Additional Comments:

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

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 of the human body as follows:						
	Mode of Operation						
Clinical Application	**B (2D Mode)**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (specify)**	**Other (specify)**
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)	P						P, Note 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal	P						P, Note 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 ; E= added under this appendix

All items marked “P” were previously cleared by 510(k) number K162972.

Additional Comments:

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

Date: April 10, 2018

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:	Randy AuCoin President and CEO
Address:	Exact Imaging, Inc. 7676 Woodbine Avenue Markham, ON L3R 2N2, Canada
E-mail:	raucoin@exactimaging.com
Telephone:	(905) 415-0030
Facsimile:	(905) 415-0031

Establishment Registration Number:

Exact Imaging, Inc.	
Registration No.	3012402886
Owner/Operator No.	100537287

Date prepared: April 5, 2018

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

Table 1: ExactVu Classifications

Classification Panel

Radiology

3) Identification of the predicate or legally marketed device:

- ExactVu High Resolution Micro-Ultrasound System (K162972) (Primary Predicate)
- TRINITY/3D-PROSTATE SUITE (K170521) by Koelis (Reference Device) (used as a Reference Device to support differences in technological characteristics)

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 comprises transducers responsible for ultrasound signal generation and recording, needle guides 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 indications for use are:

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 its predicate device. The same fundamental scientific technology and general ultrasound principles that are used for ExactVu are also used on the predicate device, and both are Track 3 devices.

Primary differences between the subject and predicate device are support for DICOM features and support for prostate biopsy workflow that includes imported MRI data to aid in image-guided targeted biopsy.

The same prostate biopsy workflow that includes imported MRI data is also used on the reference device.

Comparisons of relevant significant features are presented in two tables below, Table 2 for a comparison between the Subject Device and the Predicate Device and Table 3 for a comparison between the Subject Device and the Reference Device.

Feature	Subject Device: ExactVu 2.0	Predicate Device: ExactVu 1.0 (K162972)
Manufacturer	Exact Imaging Inc.	Exact Imaging Inc.
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 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.
Indication for use (Clinical application)	The indications for use (clinical applications) are: • Small Organ (prostate) • Transrectal The system may be used with patients of all ages, but is not designed for pediatric or fetal use.	The indications for use (clinical applications) are: • Small Organ (prostate) • Transrectal The system may be used with patients of all ages, but is not designed for pediatric or fetal use.
Modes of Operation	B-mode (2-D Grayscale Imaging, Transverse, CFM and combinations	B-mode (2-D Grayscale Imaging, Transverse, CFM and combinations
MI Indication	Yes	Yes
TI Indication	Yes	Yes
Electrical Safety	TUV, IEC 60601-1	TUV, IEC 60601-1
510(k) Track	Track 3	Track 3
Center Frequency Range	EV9C: 6.5 MHz EV29L: 22.5 MHz	EV9C: 6.5 MHz EV29L: 22.5 MHz
Transducer Types	Endocavity Linear Endocavity Curved Array	Endocavity Linear Endocavity Curved Array

Feature	Subject Device: ExactVu 2.0	Predicate Device: ExactVu 1.0 (K162972)
Measurement	Manual measurements are available on the ultrasound system, including distance, area approximations and volume calculations.	Manual measurements are available on the ultrasound system, including distance, area approximations and volume calculations.
#Transmit Channels	128 channels	128 channels
#Receive Channels	128 channels	128 channels
DICOM	Storage Storage Commitment	Not supported, see Table 3
"Fusion" implementation	Prostate biopsy workflow includes MRI data imported from USB or DVD. The user identifies anatomical markers on the ultrasound image to align the midline of the urethra, and the software uses the markers to compare with the MRI data and displays a side by side MRI/ultrasound image that follows the rotation of the transducer.	Not supported, see Table 3

Table 2: Technological Characteristics Comparison Between Subject Device and Subject Device

Feature	Subject Device: ExactVu 2.0	Reference Device: TRINITY/3D-PROSTATE SUITE (K170521)
Manufacturer	Exact Imaging Inc.	Koelis
Indication for use (Clinical application)	The indications for use (clinical applications) are: • Small Organ (prostate) • Transrectal The system may be used with patients of all ages, but is not designed for pediatric or fetal use.	TRINITY is indicted to generate ultrsaound images for structural analysis and fluid flow analysis for: • urology • gynecology • vascula • abdominal • small organs • soft tissues and • musculoskeletal exams 3D-PROSTATE SUITE, embedded on TRINITY or other KOELIS systems that do not integrate a 3D

Feature	Subject Device: ExactVu 2.0	Reference Device: TRINITY/3D-PROSTATE SUITE (K170521)
		ultrasound module, is indicated to: • process, visualize and record various 2D and 3D image modalities (such as Ultrasound Images, MRI) • Fuse images of various modalities • Display organs and perform measurements • Manage patient data • Import and export of data and images
DICOM	Storage Storage Commitment ExactVu reads MRI study data in DICOMDIR format, where MRI markup uses DICOM GSPS (Grayscale Softcopy Presentation State) allowing the ExactVu system to locate and retrieve standard DICOM tags on import. On exports to a PACS server, ExactVu uses both standard and private DICOM tags to retain all image data, needle guide overlays, measurements, annotations.	Fully integrated with Worklist and PACS communication Clinicians immediately receive patient's images from PACS. Prostate information including contours and targets and patient data are read via DICOM Worklist.
"Fusion" implementation	Prostate biopsy workflow includes MRI data imported from USB or DVD. The user identifies anatomical markers on the ultrasound image to align the midline of the urethra, and the software uses the markers to compare with the MRI data and displays a side by side MRI/ultrasound image that follows the rotation of the transducer.	The 3D-PROSTATE SUITE is embedded on the TRINITY system and may also be embedded on other Koelis systems that record images through other modalities. MR is one of the modalities is supported for fusion with live ultrasound images after being smoothly deformed to align anatomical points. The locations of lesions are displayed on an overlaid 3D map.

Table 3: Technological Characteristics Comparison Between Subject Device and Reference Device

EXACT IMAGING

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, Risk Mitigation 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 60601-2-18	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		Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic

Reference No	Recognition No	Title
		Ultrasound Equipment, American Institute of Ultrasound in Medicine

Table 4: Standards with which ExactVu Complies

Summary of Clinical Tests:
The ExactVu System, transducers and needle guides, subject of this submission, did not require clinical studies to support the determination of substantial equivalence. An analysis of clinical literature, adverse event and recall data is provided in the clinical evaluation justifies the safety and efficacy of the functionality of the ExactVu device without pre-market clinical investigation.

8) Conclusion:

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The ExactVu device and predicate device conform to applicable electrical medical 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 device.