Exact Imaging, Inc.
% Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

October 1, 2019

Re: K192303
Trade/Device Name: ExactVu™ High Resolution Micro-Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OIJ
Dated: September 23, 2019
Received: September 24, 2019

Dear Prithul Bom:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192303

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 physicians, physician assistants, sonographers and ultrasound technicians in a healthcare facility for diagnostic ultrasound imaging or fluid flow analysis of the human body in B-Mode (2D), Color Flow Imaging Modes (Color Doppler and Power Doppler) and Combined (B-Mode + CFI Modes). The indications for use are:

- Small Organ
- Transrectal
- Abdominal

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

The system is contraindicated for direct cardiac application and for ophthalmic use or any application that causes the acoustic beam to pass through the eye.

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.

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EXACT IMAGING

Date: 17-July-2019

510(k) Summary

K192303

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.

Manufacturer: **Address:**	Exact Imaging, Inc. 7676 Woodbine Avenue, Unit 15 Markham, ON L3R 2N2 Canada
Establishment Registration:	3012402886
Contact Name: **Title:**	Ms. Sam Rajkumar, MS, RAC, RN Manager, Regulatory Affairs & Quality Assurance
Phone Number:	+1 905 415 1654
Device Proprietary Name:	ExactVu™ High Resolution Micro-Ultrasound System
Device Common or Usual Name:	Diagnostic Ultrasound System with Accessories
Classification Panel:	Radiology
Product Code:	IYN, IYO, ITX, OIJ
Regulation Number:	21 CFR 892.1550, 892.1560, 892.1570
Regulation Class:	II
Regulation Description:	Ultrasonic pulsed echo imaging system, Diagnostic Ultrasound Transducers, Biopsy Needle Guide, Ultrasonic pulsed doppler imaging system

Predicate Devices:
Substantial equivalence is claimed to the following device:

Trade name	Manufacturer	510(k) Number	Date Cleared
ExactVu™ High Resolution Micro-Ultrasound System	Exact Imaging Inc.	K190995	May 10, 2019

Reference Devices:
The following reference devices have been used:

Trade name	Manufacturer	510(k) Number	Date Cleared
CIVCO Disposable Template Grid	CIVCO Medical Instruments Co., Inc.	K131161	September 17, 2013
CIVCO Poly Ultrasound Transducer Cover	CIVCO Medical Instruments Co., Inc.	K970513	June 20, 1997

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 of 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.

Intended Use /Indications for use:
The ExactVu High Resolution Micro-Ultrasound System is intended for use by qualified physicians, physician assistants, sonographers and ultrasound technicians in a healthcare facility for diagnostic ultrasound imaging or fluid flow analysis of the human body in B-Mode (2D), Color Flow Imaging Modes (Color Doppler and Power Doppler) and Combined (B-Mode + CFI Modes). The indications for use are:

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

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Summary of Technological Comparisons:

The ExactVu High Resolution Micro-Ultrasound System is an enhanced implementation of the previous FDA-cleared version of ExactVu High Resolution Micro-Ultrasound System.

The primary function of both devices is for diagnostic ultrasound imaging, data processing and guidance of puncture and biopsy. The primary difference between ExactVu High Resolution Micro-Ultrasound and the predicate device is enhanced functionality through the introduction of a new accessory and minor workflow improvements.

Main advantages compared to the predicate device are:

- Minor workflow improvements: bugs fixed and EV29L angle reset.
- Additional support for Transperineal Biopsies.

There are no known disadvantages.

ExactVu High Resolution Micro-Ultrasound System remains substantially unchanged from the predicate with respect to its intended use and performance claims.

Nonclinical Performance Testing

Verification and validation testing have been conducted on the ExactVu High Resolution Micro-Ultrasound system to ensure the safety and effectiveness of the device to perform in accordance to its intended use. The following table provides a summary of the testing performed on the ExactVu High Resolution Micro-Ultrasound.

Type	Activity	Description of Activity	Documentation Results
System Verification and Validation	Functional verification of integrated system	Test of ExactVu System and test cases developed to verify system specifications.	The ExactVu System meets all system specifications which is evident through the acceptance of Verification and Validation Results.
	Testing of resolved anomalies	Testing of anomalies present in previously released versions of the device that have been resolved in the ExactVu release.	Previous errors were tested and verified to no longer occur.
	User acceptance testing	Testing of ExactVu System to validate	The ExactVu System meets all usability

Type	Activity	Description of Activity	Documentation Results
		customer needs and intended use.	specifications which is evident through the acceptance of Verification and Validation Results.
	Human Factors Validation	Testing of critical features by intended users to determine if device is safe and effective for intended users, uses and environments per IEC 62366 and FDA Guidance: “Applying Human Factors and Usability Engineering to Medical Devices”.	The ExactVu System compiles with IEC 62366 and FDA Guidance: “Applying Human Factors and Usability Engineering to Medical Devices.”
	System Validation	Product specifications are validated by intended user in a simulated use environment to validate customer needs and intended use.	The ExactVu System meets all product specifications which is evident through the acceptance of Verification and Validation Results.
	Biocompatibility	Verify that all patient contacting materials are safe for contact with humans through conformance with ISO 10993.	All patient contact materials are biocompatible and comply with ISO 10993-1.
	Sterilization	Validation of sterilization parameters per ISO 11135 and ISO 10993-7. .	All sterilized accessories comply with ISO 11135 and ISO 10993-7.
	Medical Electrical System Safety	External testing against the requirements of IEC 60601-1 to verify electrical and mechanical safety of the system.	The ExactVu System complies with IEC 60601-1.

Type	Activity	Description of Activity	Documentation Results
	Electromagnetic Compatibility	External testing against the requirements of IEC 60601-1-2 to verify that the system operates within safe limits of emission and interference requirements.	The ExactVu System complies with IEC 60601-1-2.
	Acoustic Testing	The acoustic output was measured against requirements of IEC 60601-2-37:2015, IEC 62127-1 :2007, IEC 62359:2010 and Guidance for Industry and Food and Drug Administration Staff: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued on June 27, 2019.	The Acoustic Testing for the ExactVu System is performed and reported in compliance with IEC 60601-2-37:2015, IEC 62127-1 :2007, IEC 62359:2010 and Guidance for Industry and Food and Drug Administration Staff: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued on June 27, 2019.

Clinical Testing

This technology is not new; therefore, a clinical study was not considered necessary prior to release. The substantial equivalence of the device is supported by the non-clinical testing.

Conclusion

ExactVu High Resolution Micro-Ultrasound has been shown through comparison and performance testing to be substantially equivalent to the identified predicate device. Any technological differences do not raise new questions of safety and effectiveness.