November 9, 2022

Exo Imaging, Inc.
% Antoanela Gomard
Vice President of Quality and Regulatory Affairs
4201 Burton Drive
SANTA CLARA CA 95054

Re: K222198
Trade/Device Name: Exo Iris (El2001)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 13, 2022
Received: October 14, 2022

Dear Antoanela Gomard:

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,

Yanna S. Kang -S

Yanna Kang, Ph. D.
Assistant Director
Mammography and Ultrasound Team
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222198

Device Name

Exo Iris (EI2001)

Indications for Use *(Describe)*

Exo Iris is indicated for use by qualified and trained healthcare professionals in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organ (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial) and Ophthalmic. Modes of operation include: B-Mode, B-Mode + Color Doppler, B-Mode + M-Mode.

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.

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K222198

510(k) Summary
Prepared July 21st, 2022

Sponsor	Exo Imaging Inc. 4201 Burton Drive Santa Clara, CA, 95054
Contact Person	Antoanela Gomard Vice President of Quality and Regulatory Affairs
Telephone	650-283-0458
Email	antoanela@exo.inc
Submission Date	July 21st, 2022
Device Name	Exo Iris
Common Name	Diagnostic Ultrasound System
Trade Name	Exo Iris
Regulatory Class	II
Review Category	21CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570
Classification Panel	Radiology

Classification Name and Regulation Number Product Code:

	Regulation Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90 - IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90 - IYO
Diagnostic Ultrasound Transducer	892.1570	90 - ITX

A. Legally Marketed Predicate Devices

The predicate device is the Exo Iris, manufactured by Exo Imaging Inc. (K211527) cleared on 20th August 2021.

B. Reference Device

The reference device is the Butterfly iQ Ultrasound System, manufactured by Butterfly Network, Inc. (K202406).

C. Device Description:

The subject device, Exo Iris is a hand-held, general purpose diagnostic imaging system used to enable visualization of anatomical structures and fluid of adult and pediatric patients. The system is intended to be used by trained healthcare professionals.
The system generates 2D images using a single ultrasound transducer with broad imaging capabilities. The images are displayed on a commercial off-the-shelf mobile device (iPhone) by means of a proprietary mobile application (Exo Iris app) provided by Exo Imaging. Images can be displayed in the following modes: B-Mode, B-Mode + Color Doppler, B-Mode+ M-Mode.
The mobile application's user interface includes touchscreen menus, buttons, controls, indicators, and navigation icons that allow the operator to control the system and to view ultrasound images.

D. Intended Use / Indications for Use

The subject device, Exo Iris, is indicated for use by qualified and trained healthcare professionals in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organ (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial) and Ophthalmic.

Modes of operation include: B-mode, B-mode + Color Doppler, B-Mode+ M-Mode.

E. Substantial Equivalence

The subject device is substantially equivalent to the predicate, Exo Iris 1.0 (Exo Imaging, Redwood City, CA) cleared through 510(k) premarket notification on 08/20/2021 (K211527).

Table 1 Comparison of Indications for Use

Device Name	Predicate Device Exo Iris Ultrasound System (this submission)	Predicate Device Exo Iris Ultrasound System 510(k): K211527	Reference Device Butterfly iQ Ultrasound System 510(k): K202406
Indications for Use	Exo Iris is indicated for use by qualified and trained healthcare professionals in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organ (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial) and ophthalmic. Modes of operation include: B-mode, B-mode + Color Doppler, B-Mode + M-Mode.	Exo Iris is indicated for use by qualified and trained healthcare professionals in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies), Small Organ (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial). Modes of operation include: B-mode, B-mode + Color Doppler.	The Butterfly iQ Ultrasound System is indicated for use by trained healthcare professionals in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial) and Ophthalmic. Modes of operation include B-mode, B-mode + M-mode, B-mode + Color Doppler, B-mode + Power Doppler.
Manufacturer	Exo Imaging Inc.	Exo Imaging Inc.	Butterfly Network, Inc.

Device Name	Predicate Device Exo Iris Ultrasound System (this submission)	Predicate Device Exo Iris Ultrasound System 510(k): K211527	Reference Device Butterfly iQ Ultrasound System 510(k): K202406
510(k) number	TBD	K211527	K202406
Regulation medical specialty	Radiology	Radiology	Radiology
Product code	IYN, IYO. ITX	IYN, IYO. ITX	IYN, IYO. ITX
Regulation number	21CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570	21CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570	21CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570
Regulation description	Diagnostic Ultrasound System	Diagnostic Ultrasound System	Diagnostic Ultrasound System
Classification	II	II	II
Intended Users	Trained healthcare professionals	Trained healthcare professionals	Trained healthcare professionals
510(k) Track	Track 3	Track 3	Track 3
Imaging Modes	B-mode, B-mode + Color Doppler, B-Mode + M-Mode	B-mode / B-mode + Color Doppler	B-mode, B-mode + M-mode, B-mode + Color Doppler, B-mode + Power Doppler

Table 2. Substantial Equivalence Comparison for Technological Characteristics

Parameters	Subject Device	Predicate Device	Reference Device (K202406)
Trade Name	Exo Iris	Exo Iris	Butterfly iQ Ultrasound System
Manufacturer	Exo Imaging, Inc.	Exo Imaging, Inc.	Butterfly Network, Inc.
General Device Description			
Device type	Handheld portable diagnostic ultrasound system	Handheld portable diagnostic ultrasound system	Handheld portable diagnostic ultrasound system
Transducer Characteristics			
Array Type	Single probe 2D phased array	Single probe 2D phased array	Single probe 2D phased array
Other Relevant Similarities			
Source of Energy	Battery-operated	Battery-operated	Battery-operated
Electrical Safety	Yes, compliant with applicable electrical safety standards	Yes, compliant with applicable electrical safety standards	Yes, compliant with applicable electrical safety standards
Mechanical Safety	Meets mechanical safety standards for a class II medical device	Meets mechanical safety standards for a class II medical device	Meets mechanical safety standards for a class II medical device
Biocompatibility	Yes, compliant with ISO 10993	Yes, compliant with ISO 10993	Yes, compliant with ISO 10993
Sterility	Non-sterile	Non-sterile	Non-sterile
Display	COTS Device Display (iPhone)	COTS Device Display (iPhone)	COTS device display

Based on the comparison of indications for use and technological characteristics, the subject device is substantially equivalent to the predicate device.

E. Performance Data

All specifications for Exo Iris have been verified and validated as required by the risk analysis. All design verification and validation activities were performed by the designated individual(s) according to the company's Design Control Process and the results demonstrated that the predetermined acceptance criteria were met.

The verification and validation testing included testing to the following applicable standards:

- ANSI/AAMI ES60601-1: 2005 / (R)2012 – Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 (Edition 4.0): 2014+AMD1:2020, FCC Part 15, Subpart B Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC 60601-2-37:2007 + A1:2015, Edition 2.1 – Medical electrical equipment – Part 2: Requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
- ISO 10993:2009 Biological Evaluation of Medical Devices. Part 1
- NEMA UD-2: 2004 (R2009) Rev 3, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- IEC 62304 Edition 1.1 2015-06 Consolidated Version, Medical Device Software - Software Life Cycle Processes

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30. Exo Imaging certifies that all verification and validation activities provided in this submission were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. Successful results for the following tests were included in the submission as performance data supporting substantial equivalence:

1. Bench testing for electrical and mechanical safety in compliance with the standards cited above.
2. Bench testing for ultrasound in compliance with the standards cited above and applicable Guidance published by FDA.
3. Software testing, consisted of verification and validation testing including test cases related to off the shelf software, as well as cybersecurity features.

No human clinical data is provided to support substantial equivalence. The Exo Iris introduces no new indications for use, modes, features or technologies relative to the predicate devices that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

F. Conclusion

Potential risks were identified according to the ISO 14971. The risks were analyzed with regards to risk/benefit category and mitigations were implemented and tested as part of the performance testing described above. All risk mitigations were satisfactorily verified and validated. Where there were technological differences from the predicate, these were shown not to result in any new issues of safety or efficacy according to the performance data submitted.
Therefore, the Exo Iris Ultrasound System is substantially equivalent to the predicate device with regards to intended use and technological characteristics. Results of performance testing demonstrated that the device met the design requirements.