May 5, 2026

Healium Intelliscan Corporation
% George Hattub
Senior Medical Device Regulatory Affairs Specialist
Medicsense USA, LLC
291 Hillside Ave.
Somerset, Massachusetts 02726

Re: K261132
Trade/Device Name: Healium Intelliscan LX192LC
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 6, 2026
Received: April 6, 2026

Dear George Hattub:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
DHT8C: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261132

Please provide the device trade name(s).

Healium Intelliscan LX192LC

Please provide your Indications for Use below.

The Healium Intelliscan LX192LC is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who has the ability to conduct ultrasound scan process for evaluation by ultrasound imaging system or fluid flow analysis of the human body. The modes of operation include B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode (B+M, B+CD, B+PWD).Specific clinical applications and exam types including:

Fetal,General abdominal imaging,Pediatric,Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic,Trans-rectal,Trans-vaginal,Urology,Musculoskeletal (conventional),Musculoskeletal (superficial),OB/Gyn,Cardiac (adult),Cardiac (pediatric),Peripheral vessel ,Other (Carotid),Pulmonary,Nerve

The device is intended for use in environments where healthcare is provided by trained healthcare professionals, but not intended for use in emergency medical service, ambulance, or aircraft.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary K261132
(21 CFR 807.92)

1. Submitter Information

Healium Intelliscan Corporation
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Suite 934-G68
New York, NY 10004
United States

Contact Person:
George Hattub, Senior Regulatory Affairs Medical Device Specialist
Email: ghattub@medicsenseusa.com

2. Submission Information

Submission Type: Special 510(k) Premarket Notification
Device Name: Healium Intelliscan LX192LC
Common Name: Diagnostic Ultrasound System and Accessories
Regulation Numbers: 21 CFR 892.1550, 892.1560, 892.1570
Product Codes: IYN, IYO, ITX
Device Class: II
Review Panel: Radiology

3. Predicate Device

Predicate Device: K243226

4. Device Description

Portable ultrasound imaging system with dual-headed transducer (linear and convex), mobile application, Wi-Fi connectivity, and Doppler imaging modes.

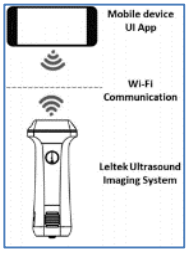
The Ultrasound Imaging System is a portable, software controlled, handheld ultrasound system used to acquire and display hi-resolution, real-time ultrasound data.

The imaging system software runs as an app on a mobile device.

The imaging system software can be download to a commercial off-the-shelf (COTS) mobile device and utilizes an icon touch-based user interface.

The imaging system consists of a wireless transducer employing Wi-Fi-based technology to communicate with traditional tablet/smartphone devices via direct Wi-Fi.

This allows the user to export ultrasound images and display them across a range portable personal device. The imaging system houses a built-in battery, multichannel beamformer, prescan converter and Wi-Fi components



5. Intended Use / Indications for Use

The Healium Intelliscan LX192LC is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who has the ability to conduct ultrasound scan process for evaluation by ultrasound imaging system or fluid flow analysis of the human body. The modes of operation include B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode (B+M, B+CD, B+PWD).Specific clinical applications and exam types including:

Fetal, General abdominal imaging, Pediatric, Small organ (thyroid, prostate, scrotum, breast),Neonatal cephalic, Trans-rectal, Trans-vaginal, Urology, Musculoskeletal (conventional), Musculoskeletal (superficial),OB/Gyn, Cardiac (adult), Cardiac (pediatric), Peripheral vessel, Other (Carotid), Pulmonary, Nerve

The device is intended for use in environments where healthcare is provided by trained healthcare professionals, but not intended for use in emergency medical service, ambulance, or aircraft.

6. Technological Characteristics

Identical to predicate in design, materials, energy source, software, and performance.

7. Substantial Equivalence

Differences limited to manufacturer name change and removal of ophthalmic indications. No impact on safety or effectiveness.

Substantial Equivalence Comparison Table

Feature	Subject Device (Healium Intelliscan LX192LC)	Predicate Device (K243226)	Comparison/Conclusion
Indications for Use	Same as predicate except removal of ophthalmic applications	Includes ophthalmic and all other indications	Narrowing of indications; does not change intended use
Intended Use	Diagnostic ultrasound imaging and fluid flow analysis	Same	Identical
Design	Handheld ultrasound system with dual-headed probe and mobile platform	Same	Identical
Materials	No change	Same	Identical
Principle of Operation	Ultrasonic transmission/reception and beamforming	Same	Identical
Energy Source	Rechargeable battery	Same	Identical
Software	No change	Same	Identical
Performance	Same imaging modes and specifications	Same	Identical
Manufacturing	Manufactured by Leltek Inc. (contract manufacturer)	Manufactured by Leltek Inc.	No change in manufacturing

8. Performance Data

The Ultrasound Imaging System has been designed, manufactured, tested, and certified to comply with the following internationally recognized standards:

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number/Date	Title of Standard
05/30/2022	19-46	ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
12/21/2020	19-36	ANSI AAMI IEC	60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
12/21/2020	5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
12/21/2020	19-38	IEC	60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
06/27/2016	12-293	IEC	60601-2-37 Edition 2.1 2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
12/23/2019	19-33	IEC	62133-2 Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems
01/14/2019	13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
07/06/2020	5-129	ANSI AAMI IEC	62366-1:2015+AMD1:2020 (Consolidated Text)	Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1
01/14/2019	2-258	ISO	10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
12/23/2016	2-245	ISO	10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
12/19/2022	2-296	ISO	10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
06/07/2021	2-291	ISO	10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
12/20/2021	5-134	ISO	15223-1 Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
12/23/2019	5-125	ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices

9. Safety and Effectiveness

No new risks introduced. Removal of ophthalmic indication reduces risk.

10. Manufacturing

Manufactured by Leltek Inc. as contract manufacturer. Healium assumes legal manufacturer responsibility.

11. Conclusion

Device is substantially equivalent to predicate and remains safe and effective.