April 8, 2022

ImaCor Inc
% Prithul Bom
Most Reponsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K220490
Trade/Device Name: ImaCor Zura Handheld ZHH-010
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, 2022
Received: April 7, 2022

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 and Part 809); 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

Jessica Lamb, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220490

Device Name
ImaCor Zura Handheld ZHH-010

Indications for Use *(Describe)*
The ImaCor Zura Handheld ZHH-010 is a software-based handheld ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging using the ImaCor ClariTEE probe. (Cardiac, TEE)

The system is intended for use in critical care environments where healthcare is provided by trained healthcare professionals.

It is not for pediatric use (Less than 18 years of age)
It is not for use in EMS settings.

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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K220490

510(k) Summary

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

Submitter: Richard Lanzillotto

Director of Regulatory Affairs
ImaCor Inc.
50 Jericho Turnpike Suite 105, Jericho, NY 11753:
Tel: (1)-631-255-7183, rclanzillotto@gmail.com
Fax: N/A

Date Prepared: Sept 1, 2021, Modified Nov 1, 2021

2. Name of the device, including the trade or proprietary name, if appliable, the common or usual name, and the classification, if known:

Device Name: ImaCor Zura Handheld ZHH-010

Common Name: Diagnostic Ultrasound System and Accessories

Classification: Class II

Classification Names:

21 CFR Section	Classification Name	Product Code
892.1550	Ultrasonic Pulsed Doppler Imaging System	90 IYN
892.1560	Ultrasonic Pulsed Echo Imaging System	90 IYO
892.1570	Diagnostic Ultrasound Transducer	90 ITX

3. Substantially Equivalent Devices: [Primary Predicate Device]

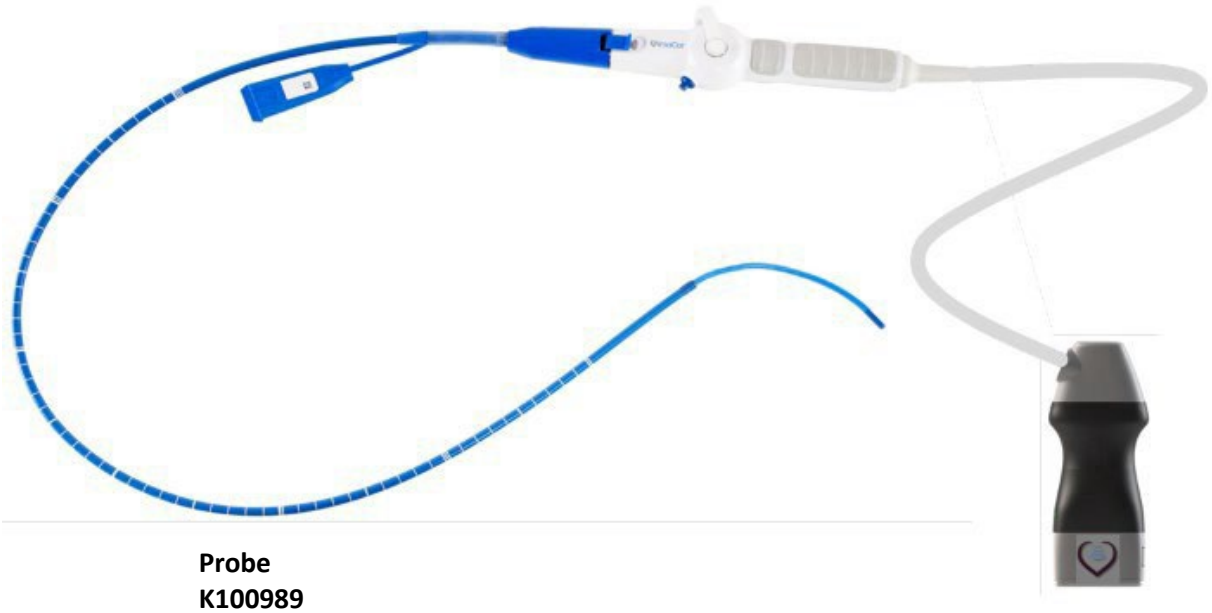
Device Name	510(k) Number
Clarius Ultrasound Scanner Model C3HD	K192107

Device Description

The ImaCor Zura Handheld ZHH-010 is a portable, cardiac, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) Android™ device. The scanner is Bluetooth and Wi-Fi- based, communicating with a traditional tablet/smartphone via direct Wi-Fi to allow users to export ultrasound images and display in different modes of operation. The ImaCor Zura Handheld ZHH-010 houses a battery and internal power supplies, multichannel beamformer, pre-scan converter and Wi-Fi components. The battery is

removable and comes with a separate charger.

The system is a transportable (handheld) ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals. The ImaCor Zura Handheld ZHH-010 is not to be used in a fixed- or rotary-winged air ambulance.



Probe
K100989

ZHH
Scanner

Figure 1: ImaCor Zura Handheld ZHH-010and ClariTEE probe

Piezoelectric material in the system's transducer (ClariTEE probe) transmits high frequency, non-ionizing sound waves to the designated cardiac region of the body and converts the subsequent echoes detected into electronic signals to construct an image of the internal structures of an anatomical field. This image is sent wirelessly to an external Android viewing device on which the image can be displayed. Communication between the scanner and the compatible viewing device is performed via Wi-Fi Direct® (Ad-Hoc mode with security) for easy pairing.

The ImaCor Zura Handheld ZHH-010 product components include:

1. Software:
   - SOUP Imaging App for Android
2. Transducers/Scanners:
   - ImaCor ClariTEE probe (TEE probe);
3. Accessories:
   - ImaCor Battery (Li-ion);

ImaCor Battery Charger;

- ImaCor Fan
- Medical Power Supply (off-the-shelf power adaptor from GlobTek, Inc.; Model Number WR9QA3200USBNMEDR6B; approved in the US).

The concept of the ImaCor Zura Handheld ZHH-010 transducers and software is to provide an easy to use, high-performance, low-cost ultrasound platform for diagnostic imaging. It is indicated for diagnostic ultrasound imaging in using the ImaCor ClariTEE probe (cardiac, TEE) applications. The ImaCor Zura Handheld ZHH-010 is intended for use in environments where healthcare is provided by trained healthcare professionals.

Regulatory History

The new device submission is similar to a device cleared under – K192107 by the same manufacturer now acting as OEM to ImaCor. The change of this new submission from this manufacturer's own product line is the output probe is tethered to the scanner body as opposed to the transducer being integrated to the scanner body. Otherwise, All electrical and mechanical aspects of thebeamformer are identical to the predicate device. Appropriate changes have been made to mitigate risks and ensure effectiveness of these new features. The software app is developed by the original manufacturer with no changes made by ImaCor. Therefore, it is SOUP by ImaCor's perspective.

Intended Use/IndicationsforUse

The ImaCor Zura Handheld ZHH-010 is a software-based handheld ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging using the ImaCor ClariTEE probe (Cardiac, TEE).

The system is intended for use in critical care environments where healthcare is provided by trained healthcare professionals. It is not for pediatric use (Less than 18 years of age). It is not for use in EMS settings.

Primary PredicateDevice

Equivalent devices are referred to as predicate devices in alignment with the FDA's standard terminology for comparable devices. The predicate device selected to demonstrate equivalence is:

1.	**Device Name** Clarius Ultrasound Scanner Model C3HD	**FDA 510(k) Number** K192107

The beamformer in the ImaCor Zura Handheld ZHH-010 is mechanically and electrically identical to the predicate device. However, the output probe for the predicate device is integrated into the scanner body. The ImaCor Zura Handheld ZHH-010 device probe (ClariTEE) is not integrated into the scanner body but is connected to the scanner body by a tether.

Reference Device

A reference device is chosen as it is technologically similar to the new device in terms of its probe output. The reference device selected is:

1.	**Device Name** ImaCor Zura TEE System with ClariTEE probe	**FDA 510(k) Number** K100989

The ImaCor Zura Handheld ZHH-010 device is for use with the ClariTEE probe which was cleared in K100989 (06/25/2010). The ImaCor-Zura TEE (reference device) and ImaCor Zura Handheld ZHH-010 are both diagnostic ultrasound systems for cardiac adult applications. They both use the ClariTEE probe; a

Transesophageal Echo (TEE) transducer.

Determination of Substantial Equivalence

The ImaCor Zura Handheld ZHH-010 employs the same fundamental scientific technology as that cleared with predicate device, Clarius Ultrasound Scanner (K192107). All indications for use introduced by the ImaCor Zura Handheld ZHH-010 are similar to thepredicate device. A comparison table is provided below:

Criteria for Comparison	**ImaCor Zura Handheld ZHH-010 (Subject Device)**	**Clarius Ultrasound Scanner C3HD (K192107) (Predicate Device)**
Portability	Portable ultrasound system	Portable ultrasound system
Power Source	Removable battery (Li-ion)	Removable battery (Li-ion)
Display	Android mobile device	iOS or Android mobile device
Wireless Capability	Communicates wirelessly via Wi-Fi and Bluetooth	Communicates wirelessly via Wi-Fi and Bluetooth
501(k) Track	Track 3	Track 3
Transducer Types	− Linear Array	− − Linear Array −
Intended Use	Diagnostic ultrasound imaging	Diagnostic ultrasound imaging
Indications for Use	-Trans-esophageal (Cardiac) -Cardiac adult - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - - - - - **Cardiac adult** - Other indications not relevant to discussion - - -
Modes of Operation	− B-mode	− **B-mode** − M-mode − Color Doppler − Power Doppler − PWD − CWD − Combined (B+M; B+CD; B+PD;B+PWD)

Cybersecurity	Same as SOUP software	Accepted via K192107

Equivalency Conclusion

The subject device does not introduce any new technology or indications for use; therefore, the system is similar to the predicate device.

Non-Clinical Performance Data

Nonclinical performance tests show compliance to the following standards:

Reference No.	Year	Title
IEC 60601-1	2005/(R)2012 A1:2012 C1:2009(R)2012 A2:2010(R)2012	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
ANSI/AAMI/IEC 62304	2006	Medical device software – Software life cycle processes.
CAN/CSA-C22.2 No. 60601-1-6:11	2011	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (Adopted IEC 60601-1- 6:2010, third edition, 2010-01)
CAN/CSA-C22.2 No. 60601-1:14	2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Capability - Requirements and tests
IEC 60601-1-6	2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-2-37 AMDI	2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

Clinical Performance Data

The ImaCor Zura Handheld ZHH-010 did not require clinical testing to establish substantial equivalenceto the predicate devices indicated.

Quality Assurance Measures

Quality assurance measures applied to the system design and development include, but were notlimited to risk analysis, verification and validation, product specifications, and design reviews.

Conclusion

This device is an OEM modification of an existing cleared device using technologies that exist on the market today. The development and testing conducted on the device ascertain that it is safe for use by qualified physicians. The ImaCor Zura Handheld ZHH-010 does not introduce indications for use, technological features, or system characteristics that are not seen in its predicate or reference devices; therefore, the device is similar in safety and effectiveness to these predicate devices.