Crystalline Medical
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

June 25, 2021

Re: K203657
Trade/Device Name: Vu-Path Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: June 16, 2021
Received: June 17, 2021

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)*
K203657

Device Name
Vu-Path Ultrasound System

Indications for Use *(Describe)*
The Vu-Path Ultrasound System with associated probe and accessories provide ultrasound guidance for the placement of needles and catheters in vascular structures adults aged 22 and older. Ultrasound imaging of vascular structures and surrounding tissue may also be performed. The ultrasound probe is only intended to be placed on the surface of the skin and should not be advanced percutaneously. The device provides B-Mode and Color Doppler modes of operation.

The Vu-Path Ultrasound system needle guidance technology is indicated for use by appropriately-trained healthcare professionals to provide them with visual tools for passive tracking of a needle with respect to ultrasound image data.

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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510(k) Summary - K203657
Prepared June 8, 2021

Sponsor:	Crystalline Medical 48890 Milmont Drive, Suite 106D Fremont CA 94538
Contact Person:	Ivan Ma
Telephone:	510-270-8234
Submission Date:	June 8, 2021
Device Name:	Vu-Path Ultrasound System
Common Name:	Ultrasonic imaging system; Diagnostic ultrasonic transducer
Trade Name:	Vu-Path Ultrasound System

Classification:

Regulatory Class:	II
Review Category:	21CFR 892.1550, 892.1560 and 892.1570 (IYN, IYO, ITX)
Classification Panel:	Radiology

A. Legally Marketed Predicate Devices

The predicate device is the Site~Rite 6 Ultrasound System (K142443) Manufactured by C.R. Bard, Inc.

B. Device Description and List Of Device Components and Accessories:

The Vu-Path Ultrasound System employs the same core scientific technology as the other ultrasound devices: digital acquisition, processing, analysis and display capability. Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and shown on the device display. The Vu-Path is designed primarily to assist physicians in gaining vascular access to major veins and arteries. The system consists of a beamformer and a transducer that operates in two modes, B-Mode and Color Doppler. A single USB connection transfers the information between the beamformer and a user provided computer with display. The application software is installed on the user provided computer. The Vu-Path needle guide attaches over the sheathed transducer and has an integral needle channel that provides a path for a needle to be introduced into the target location.

REF #	Description
BF-100	Vu-Path Beamformer
TW-200	Vu-Path Transducer
NG-100	Sterile Needle Guide

C. Indications for Use/Intended Use

The Vu-Path Ultrasound System with associated probe and accessories provide ultrasound guidance for the placement of needles and catheters in vascular structures adults aged 22 and older. Ultrasound imaging of vascular structures and surrounding tissue may also be performed. The ultrasound probe is only intended to be placed on the surface of the skin and should not be advanced percutaneously. The device provides B-Mode and Color Doppler modes of operation.

The Vu-Path Ultrasound system needle guidance technology is indicated for use by appropriately-trained healthcare professionals to provide them with visual tools for passive tracking of a needle with respect to ultrasound image data.

D. Discussion of Similarities or Differences

The follow tables compare key characteristics of the predicate device and the subject device.

	Predicate Device Site~Rite 6 Ultrasound System (K142443) Manufactured by C.T, Bard, Inc.	**Subject Device Vu-Path Ultrasound System**	**Comments**
Regulation number	21CFR 892.1560 and 892.1570	21CFR 892.1550, 892.1560, 892.1570	The difference has no impact to safety and effectiveness.
Regulation description	Ultrasonic imaging system; Diagnostic ultrasonic transducer	Ultrasonic imaging system; Diagnostic ultrasonic transducer	Same
Review panel	Radiology	Radiology	Same
Product code(s)	(IYO, ITX)	(IYN, IYO, ITX)	The difference has no impact to safety and effectiveness.
Number of transducers	1 linear transducer	1 linear transducer	Same
Transducer characteristics	Linear	Linear Phased Array	The difference has no impact to safety and effectiveness.
Modes	B Mode, Needle Guidance Imaging	B Mode, Needle Guidance Imaging, Color Doppler	The difference has no impact to safety and effectiveness.
Needle guide capability	Yes	Yes	Same

Means of providing visual tools	Magnetic resonance sensor + software	Known mechanical relationship + software	The difference has no impact to safety and effectiveness.
Electrical Safety	60601-1	60601-1	Same
Electromagnetic Compatibility	60601-1-2	60601-1-2	Same
Performance Standard	60601-2-37	60601-2-37	Same

Performance testing demonstrates that the differences in technological characteristics between the subject device and the predicate device, do not raise additional questions of safety or effectiveness.

E. Performance Data

Performance testing with a statistically significant sample size was conducted to demonstrate equivalent performance of the subject device to the predicate.

The comparison of specifications and the performance data submitted demonstrate that the technological characteristics of the subject device are substantially equivalent to the predicate device and do not raise new issues of safety and efficacy.

Summary of Non-Clinical Tests

ISO 14971	Application of risk management to medical devices
AAMI 60601-1	Medical electrical equipment- General requirements for basic safety and essential performance
IEC 60601-1-2	Electromagnetic disturbances
IEC 60601-2-37	Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment
IEC 62304	Medical device software - Software life-cycle processes
ISO 10993	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30. Crystalline Medical 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
3. Software testing, consisted of verification and validation testing in compliance with ISO 62304, including test cases related to off the shelf software, as well as cybersecurity features

Summary of Clinical Tests:

The subject of this premarket submission, the Vu-Path Ultrasound System, did not require clinical studies to support substantial equivalence.

F. Conclusion

Potential risks were identified according to the ISO 14971 Standard process. The risks were analyzed with regard 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.