

K243178 Digital Color Doppler Ultrasound Imaging System (Apogee C1)

Mar 31, 2025
182 days to decisionK243178 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k243178/>

SUBMISSION DETAILS

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Sep 30, 2024 |
| Decision date | Mar 31, 2025 |
| Days to decision | 182 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Digital Color Doppler Ultrasound Imaging System (Apogee C2); Digital Color Doppler Ultrasound Imaging System (Apogee C3); Digital Color Doppler Ultrasound Imaging System (Apogee C5); Digital Color Doppler Ultrasound Imaging System (Apogee K1); Digital Color Doppler Ultrasound Imaging System (Apogee K2); Digital Color Doppler Ultrasound Imaging System (Apogee K3); Digital Color Doppler Ultrasound Imaging System (Apogee K5); Di |

APPLICANT

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| Company | Shantou Institute of Ultrasonic Instruments Co., Ltd. |
| Location | Shantou, CN |
| Contact | Zeqin Chen |
| 510(k) history | 2 submissions · 2 cleared · 2024-2025 |

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