

K243298 Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound SystemApr 3, 2025
167 days to decisionK243298 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k243298/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 18, 2024
Decision date	Apr 3, 2025
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carbon (Shenzhen) Medical Device Co., Ltd.
Location	Shenzhen, CN
Contact	Min Ye
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Linnwell International Certification Consulting Co., Ltd.
Contact	Yuling Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243298/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026