

**K261272 ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/
ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/
DF-41E Diagnostic ultrasound system**

Jul 23, 2026
97 days to decision

K261272 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k261272/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 17, 2026
Decision date	Jul 23, 2026
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Esonic Technology (Wuhan) Co., Ltd.
Location	Wuhan, CN
Contact	Souquet Jacques
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k261272/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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