

K191347 Paragon XHD Diagnostic Ultrasound SystemFeb 7, 2020
263 days to decisionK191347 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k191347/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | May 20, 2019 |
| Decision date | Feb 7, 2020 |
| Days to decision | 263 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen Wisonic Medical Technology Co. , Ltd. |
| Location | Shenzhen, CN |
| Contact | Jiang Xiaosan |
| 510(k) history | 7 submissions · 7 cleared · 2018-2023 |

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