

K200136 Shear Wave Quantificational Ultrasound Diagnostic System

Mar 17, 2020
56 days to decision

K200136 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k200136/>

SUBMISSION DETAILS

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Jan 21, 2020 |
| Decision date | Mar 17, 2020 |
| Days to decision | 56 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Wuxi Hisky Medical Technologies Co., Ltd. |
| Location | Wuxi, CN |
| Contact | Jinhua Shao |
| 510(k) history | 5 submissions · 5 cleared · 2018-2025 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k200136/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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