

K192170 VistaScan USB Ultrasound Imaging SystemJan 23, 2020
164 days to decisionK192170 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k192170/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Aug 12, 2019 |
| Decision date | Jan 23, 2020 |
| Days to decision | 164 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Emagine Solutions Technology, LLC |
| Location | Tucson, AZ, US |
| Contact | Courtney Williams |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------|
| Consulting firm | leanRAQA, LLC |
| Contact | Michelle Lott |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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