

**K170474 Reprocessed SoundStar 3D Diagnostic Ultrasound Catheter**Jun 16, 2017  
120 days to decisionK170474 · Product code: **OWQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k170474/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Reprocessed Intravascular Ultrasound Catheter (OWQ) |
| Date received         | Feb 16, 2017  |
| Decision date         | Jun 16, 2017  |
| Days to decision      | 120 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Innovative Health, LLC</b>           |
| Location       | Scottsdale, AZ, US                      |
| Contact        | Amy Stoklas-Oakes                       |
| 510(k) history | 48 submissions · 48 cleared · 2016-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170474/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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