

K202456 M5 RecorderDec 29, 2020
124 days to decisionK202456 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k202456/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Recorder, Magnetic Tape, Medical (DSH) |
| Date received | Aug 27, 2020 |
| Decision date | Dec 29, 2020 |
| Days to decision | 124 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Global Instrumentation, LLC |
| Location | Manlius, NY, US |
| Contact | Jason DeMaso |
| 510(k) history | 5 submissions · 5 cleared · 2005-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Accelerated Device Approval Services |
| Contact | Rafael Aguila |

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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