

K161507 Cianna Medical SAVI Scout Reflector and SAVI Scout SystemJul 29, 2016
58 days to decisionK161507 · Product code: **PDW** · Radiology
Source: <https://www.510kdatabase.net/k161507/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Internal Tissue Marker (PDW) |
| Date received | Jun 1, 2016 |
| Decision date | Jul 29, 2016 |
| Days to decision | 58 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cianna Medical, Inc. |
| Location | Aliso Viejo, CA, US |
| Contact | GARY MOCNIK |
| 510(k) history | 8 submissions · 6 cleared · 2008-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161507/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026