

K191813 MobileDiagnost wDR 2.2Aug 2, 2019
28 days to decisionK191813 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k191813/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, X-ray, Mobile (IZL) |
| Date received | Jul 5, 2019 |
| Decision date | Aug 2, 2019 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sedecal., Sa. |
| Location | Deer Field, IL, US |
| Contact | Maria Luisa Gomez De Agüero |
| 510(k) history | 26 submissions · 26 cleared · 2002-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191813/> 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 14, 2026