

K133966 MODEL-BASED RSA SOFTWAREMar 6, 2014
72 days to decisionK133966 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k133966/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Dec 24, 2013 |
| Decision date | Mar 6, 2014 |
| Days to decision | 72 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Halifax Biomedical, Inc. |
| Location | Dundas, CA |
| Contact | DANIEL KAMM |
| 510(k) history | 5 submissions · 5 cleared · 2009-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133966/> 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 June 18, 2026