

K161382 LVivo Software ApplicationJul 28, 2016
71 days to decisionK161382 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k161382/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | May 18, 2016 |
| Decision date | Jul 28, 2016 |
| Days to decision | 71 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Diacardio, Ltd. |
| Location | Somerset, MA, US |
| Contact | Michal Yaacobi |
| 510(k) history | 2 submissions · 2 cleared · 2013-2016 |

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