

**K142919 EXA**Dec 16, 2014  
69 days to decisionK142919 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k142919/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Special                                      |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Oct 8, 2014                                  |
| Decision date         | Dec 16, 2014                                 |
| Days to decision      | 69 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Viztek, LLC</b>                    |
| Location       | Naples, FL, US                        |
| Contact        | Josip Cermin                          |
| 510(k) history | 6 submissions · 6 cleared · 2011-2016 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142919/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026