

**K012327 CSIST DICOM GATEWAY/IMAGE MANAGER**Dec 20, 2001  
150 days to decisionK012327 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k012327/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Jul 23, 2001                                 |
| Decision date         | Dec 20, 2001                                 |
| Days to decision      | 150 days                                     |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Csist</b>                          |
| Location       | Denton, TX, US                        |
| Contact        | CARL ALLETO                           |
| 510(k) history | 1 submissions · 1 cleared · 2001-2001 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012327/> 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 19, 2026