

**K223465 RadianceTx Radionuclide Brachytherapy Source**Jan 11, 2023  
55 days to decisionK223465 · Product code: **KXK** · Radiology  
Source: <https://www.510kdatabase.net/k223465/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Source, Brachytherapy, Radionuclide (KXK) |
| Date received         | Nov 17, 2022                              |
| Decision date         | Jan 11, 2023                              |
| Days to decision      | 55 days                                   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Statement                                 |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Radiance Therapeutics, Inc.</b>    |
| Location       | Tucson, AZ, US                        |
| Contact        | Laurence Marsteller                   |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223465/> 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 28, 2026