

**K190296 GammaTile**Mar 13, 2019  
30 days to decisionK190296 · Product code: **KXK** · Radiology  
Source: <https://www.510kdatabase.net/k190296/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Feb 11, 2019
Decision date	Mar 13, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Gt Medical Technologies</b>
Location	Tempe, AZ, US
Contact	Jessica Newhard
510(k) history	3 submissions · 3 cleared · 2019-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190296/> 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 26, 2026