

K133922 GENTLECARE AR APPLICATORApr 18, 2014
116 days to decisionK133922 · Product code: **JAQ** · Radiology
Source: <https://www.510kdatabase.net/k133922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Dec 23, 2013
Decision date	Apr 18, 2014
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gc Medtech, LLC
Location	Lutsen, MN, US
Contact	GREGORY MATHISON
510(k) history	2 submissions · 2 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133922/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026