

**K202267 Sirius MRI Markers, Cs-131 Preloaded Strands with
Sirius MRI Markers in 18 Gauge Needles**Dec 31, 2020
142 days to decisionK202267 · Product code: **KXK** · Radiology
Source: <https://www.510kdatabase.net/k202267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Aug 11, 2020
Decision date	Dec 31, 2020
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Isoray Medical, Inc.
Location	Richland, WA, US
Contact	Leslie White
510(k) history	5 submissions · 5 cleared · 2009-2020

REGULATORY CONSULTANT

Consulting firm	Grace Powers - Powers Regulatory Consulting
Contact	Grace Powers

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202267/>; 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 June 15, 2026